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 m ore 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"

14-12-2025

Saudi Food and Drug Authority (SFDA) – Safety Signal of Baricitinib and the Risk of Fracture

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

Introduction

Baricitinib is a Janus kinase (JAK) inhibitor indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more TNF blockers. Its also indicated for the treatment of adult patients with severe alopecia areata [1] A fracture is a break in a bone. Most fractures result from a single, significant force applied to normal bone. Fractures may be either: Open: The overlying skin is disrupted, and the broken bone is in communication with the environment via a skin wound, or Closed: The overlying skin is intact. [2] The aim of this review is to evaluate the risk of Fracture associated with the use of Baricitinib 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 Fracture and Baricitinib use. The search conducted on December 2025.

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 10 global case-reports while no local cases found. The authors used signal detection tool (Vigilyze) to retrieve global cases. [3] Authors also applied WHO-UMC causality assessment criteria on all extracted ICSRs. [4] Among them, one case was probably linked to Baricitinib, while the remaining nine 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 (0.3) for this drug/ADR combination which reflects positive statistical association. [4]

Literature: The signal team conducted a literature search to identify publications linking this adverse drug reaction to Baricitinib. The search identified a published study suggesting a possible association between the drug and this potential risk. [5]

Conclusion

The weighted cumulative evidence identified from assessed cases, disproportionality analysis and literature are suggestive for causal association between Baricitinib and Fracture. 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:

1- Nih.gov. (2024). DailyMed - OLUMIANT- baricitinib tablet, film coated. [online] Available at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=866e9f35-9035-4581-a4b1-75a621ab55cf

2- Campagne, D. (2022). Overview of Fractures - Injuries; Poisoning. [online] MSD Manual Professional Edition. Available at: https://www.msdmanuals.com/professional/injuries-poisoning/fractures/overview-of-fractures.

3- Vigilyze.who-umc.org. 2025. [online] Available at: https://vigilyze.who-umc.org/

4- World Health Organization WHO (2013). WHO-UMC system for standardised case causality assessment. Available at https://www.who.int/publications/m/item/WHO-causality-assessment

5- Martinez de la Torre, A., Clausen, A.B., Burden, A.M. et al. Fracture-Related Safety Reporting of JAK Inhibitors: An Analysis from the WHO Global VigiBase. Drug Saf 48, 191–201 (2025). https://doi.org/10.1007/s40264-024-01490-w