Saudi Food & Drug Authority (SFDA)
Safety Communication

2/9/2020

Baricitinib (Olumiant®) and increased risk of diverticulitis: Recommendations for Healthcare Professionals from the SFDA

Baricitinib (Olumiant®) is a disease-modifying antirheumatic drug (DMARD) that selectively inhibits Janus kinase (JAC) enzyme. Baricitinib (Olumiant®) was approved by the Saudi Food and Drug Authority (SFDA) in 2018 for the treatment of moderate to severe active rheumatoid arthritis in adult patients who have responded inadequately to other DMARDs.

The SFDA would like to notify healthcare providers that diverticulitis was reported internationally with the use of baricitinib in clinical trials and post-marketing setting. The majority of cases diverticulitis with the use of baricitinib had known risk factors for diverticulitis, including, a medical history of diverticulitis and/or chronic use of non-steroidal anti-inflammatory drugs (NSAIDs), corticosteroids or opioids.

SFDA recommendations for healthcare providers:

- The majority of internationally reported cases occurred in patients who were concomitantly taking medications associated with an increased risk of diverticulitis.
- Use baricitinib with caution in patients with history of diverticular disease and in patients who are using long-term concomitant medications that associated with an increased risk of diverticulitis such as NSAIDs, corticosteroids, and opioids.
- Patients on baricitinib should be advised to seek immediately for medical counselling in case they experience abdominal pain with fever, nausea and vomiting or other signs of diverticulitis.
- Please monitor the patients who take baricitinib for any abdominal signs and symptoms to early evaluate the case and identify diverticulitis or gastrointestinal perforation.
- Be aware that diverticulitis has also reported with tofacitinib (Xeljanz®), another JAK inhibitor that indicated for treating adult patients with moderately to severely active rheumatoid arthritis.

The SFDA urges healthcare professionals to report ADEs via any of the following contact information:

National Pharmacovigilance Center (NPC)
Saudi Food and Drug Authority - Drug sector
4904 Northern ring branch rd. - Hitteen District
Riyadh 13513 - 7148
Kingdom of Saudi Arabia

Reporting hotline: 19999
Email: npc.drug@sfda.gov.sa
Webpage: http://ade.sfda.gov.sa
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