Direct Healthcare Professional Communication

August 2021

Baricitinib - This medicinal product is subject to additional monitoring

Dear Healthcare Professional,

The General Administration for Pharmaceutical Vigilance of the Central Administration for Pharmaceutical Care at The Egyptian Drug Authority would like to inform you of the following:

Summary:

- Baricitinib is a selective and reversible inhibitor of Janus kinase (JAK)1 and JAK2. In isolated enzyme assays, baricitinib inhibited the activities of JAK1, JAK2, Tyrosine Kinase 2 and JAK3 with IC50 values of 5.9, 5.7, 53 and > 400 nM, respectively.
- **Rheumatoid arthritis**
  Baricitinib is indicated for the treatment of moderate to severe active rheumatoid arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more disease-modifying anti-rheumatic drugs. Olumiant may be used as monotherapy or in combination with methotrexate
- **Atopic Dermatitis**
  Baricitinib is indicated for the treatment of moderate to severe atopic dermatitis in adult patients who are candidates for systemic therapy.

Background on the safety concern

Risks associated with the use of Baricitinib:

- Pregnancy and breast feeding (Baricitinib must not be used during pregnancy, and should not be used in women who are breast feeding or intend to breast feed)
- Infections (Baricitinib increases the potential risk of infections, and viral reactivation)
- Changes in lipid parameters (increases in total cholesterol, LDL cholesterol and HDL cholesterol were observed at 12 weeks. Mean total and LDL cholesterol increased through week 52)
- Venous thromboembolism (Events of deep venous thrombosis (DVT) and pulmonary embolism (PE) have been reported in patients receiving baricitinib. baricitinib should be used with caution in patients with risk factors for DVT/PE, such as older age, obesity, a medical history of DVT/PE, or patients undergoing surgery and immobilization)

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Additional monitoring

- Medicines with the black triangle are being monitored even more closely than others; this is generally because there is less information available about them compared with other medicines.
- Baricitinib 2mg &4mg is subjected to additional monitoring; this will allow quick identification of new safety information.
- **Healthcare professionals are asked to report any suspected adverse reactions from Baricitinib via The Egyptian Pharmaceutical Vigilance Center or Marketing authorization holder**

References

EMC

https://www.medicines.org.uk/emc/product/2434/smpc#gref
https://www.medicines.org.uk/emc/product/2434/pil
https://www.medicines.org.uk/emc/rmm/1864/Document
https://www.medicines.org.uk/emc/rmm/766/Document

Call for reporting

Healthcare professionals are asked to report any suspected adverse reactions via the Egyptian reporting system:

Name: General Administration for Pharmaceutical Vigilance

Email: pv.followup@edaegypt.gov.eg

Online reporting: https://primaryreporting.who-umc.org/EG
QR Code:

Hotline: 15301

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