olumiant®
(baricitinib) tablets

PRESCRIBING GUIDANCE FOR RHEUMATOID ARTHRITIS

Lilly | RHEUMATOLOGY

This document is approved by the Executive Directorate of Pharmacovigilance at SFDA
NOV, 2022 v3

Healthcare Professional Education Material:

Information Material for Healthcare Professionals Prescribing Olumiant® (baricitinib)

This document contains important information to assist the initial discussion with your patients when prescribing Olumiant. It should be read in conjunction with the enclosed Summary of Product Characteristics (SmPC).

Olumiant is a selective and reversible JAK1/2 inhibitor indicated for the treatment of rheumatoid arthritis (RA).
The background information and points for discussion here provide context and appropriate risk management for key safety aspects of the prescribing information, namely:

- **Pregnancy and breast feeding**
- **Infections**
- **Changes in lipid parameters**
- **Venous Thromboembolism**

As part of the initial discussion with your patients, please:

- Provide a **Patient Alert Card** to each patient
- Advise them that the Card should be read in conjunction with the **Patient Information Leaflet**.

Pregnancy and Breast Feeding

Please discuss these points with your female patients if they are of child bearing potential:

- **Olumiant must not be used during pregnancy**.
  There is insufficient experience with Olumiant at this time to determine whether it can be safely used in pregnancy.
- **Olumiant should not be used in women who are breast feeding or intend to breast feed**.
  As there is no information on the excretion of Olumiant into human milk, it is unknown if it is safe to use during breast feeding.

As a result, it is important to:

- **Ask** patients if they are, might be, or intend to become pregnant, or are breast feeding prior to prescribing Olumiant.
- **Advise** women to use effective contraception both during treatment and for at least 1 week after discontinuing treatment, taking into account the short half-life of Olumiant.

Background pre-clinical safety information

As described in sections 4.6 and 5.3 of the SmPC, animal studies showed reduced foetal growth and skeletal malformations at exposures ≥10 times the human exposure.

As there are no adequate data on the use of Olumiant in human pregnancy, the implications of these non-clinical findings on use in women are not known. Therefore, the advice provided on use in pregnancy is given as a precautionary measure.

EULAR recommendations

The EULAR "Points to Consider for Use of Antirheumatic Drug Before Pregnancy, and During Pregnancy and Lactation" provides independent expert advice to support family planning discussions and could provide another useful reference source.

Infections

Olumiant increases the potential risk of infections, and viral reactivation.

Consistent with usual practice in treating patients with RA, it is important to instruct patients to seek immediate medical attention if signs or symptoms suggesting infection appear, in order to ensure rapid evaluation and appropriate treatment.

If an infection develops, monitor the patient carefully and:

- Temporarily interrupt Olumiant in case of herpes zoster infection or for any infection that is not responding to standard therapy. Do not resume Olumiant treatment until the infection resolves. Do not resume Olumiant treatment until the infection resolves.
- Screen patients to rule out active tuberculosis and active viral hepatitis before starting Olumiant.
- Do not use live, attenuated vaccines during, or immediately prior to, Olumiant therapy.

- **Advise** Advise patients to inform you immediately if they think they could be pregnant or if pregnancy is confirmed in order to facilitate the appropriate discussions on the potential risks.

These points are in line with independent expert EULAR recommendations* (See overleaf)

* Götestam Skorpen C et al. The EULAR points to consider for use of antirheumatic drugs before pregnancy, and during pregnancy and lactation. Ann Rheum Dis. 2016;75(5):795-810

Changes in Lipid Parameters

In RA clinical trials, dose-dependent increases in LDL and HDL cholesterol were observed at 12 weeks with no change in the LDL/HDL ratio. Lipid levels remained stable after 12 weeks. The longterm consequences of these changes are unknown.

As a result of these considerations, it is important to:

- Assess lipid parameters approximately 12 weeks following initiation of Olumiant therapy.
- Manage patients according to clinical guidelines for hyperlipidaemia thereafter.
- Correct elevations in LDL cholesterol with statin treatment, if necessary.

Venous Thromboembolism

Events of deep venous thrombosis (DVT) and pulmonary embolism (PE) have been reported in patients receiving Olumiant. Olumiant 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 immobilisation. If clinical features of DVT/PE occur, Olumiant treatment should be discontinued and patients should be evaluated promptly, followed by appropriate treatment.

As a result, it is important to advise patients to inform you immediately if any of the following symptoms are experienced:

- **Swelling or pain in one leg**
- **Warmth or redness in one leg**
- **Shortness of breath which is unexpected**
- **Rapid breathing**
- **Chest pain**

To report any side effects, please contact:
The National Pharmacovigilance Centre (NPC)
Saudi Food and Drug Authority (SFDA)

Unified number: 19999

Email: npc.drug@sfda.gov.sa

Website: https://ade.sfda.gov.sa/

Or

Pharmacovigilance department at
Eli Lilly and Company

Email:
Saudi_Pharmacovigilance@lilly.com

Phone number: 00966114617845