IMPORTANT RISK MINIMIZATION INFORMATION FOR HEALTHCARE PROFESSIONALS PRESCRIBING OLUMIANT® (BARICITINIB)

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

Olumiant (Baricitinib) is a selective and reversible janus kinase (JAK)1/2 inhibitor indicated for the treatment of moderate to severe active rheumatoid arthritis (RA) in adult patients and active juvenile idiopathic arthritis (JIA) in patients 2 years of age and older who have responded inadequately to, or who are intolerant to one or more disease -modifying anti-rheumatic drugs.

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

- Provide a **Patient Alert Card** to each patient and explain that it contains important information they should be aware of before and during treatment with baricitinib.
- Advise them that the Card should be read in conjunction with the **Patient Information Leaflet.**

The recommended dose of baricitinib is 4 mg once daily.

A dose of 2 mg once daily is recommended for patients:

- at higher risk of venous thromboembolism, major adverse cardiovascular events (MACEs), and malignancy
- aged 65 years and older, and
- with a history of chronic or recurrent infections.
- A dose of 4 mg once daily may be considered for patients who do not achieve adequate control of disease activity with 2 mg once daily dose.
- A dose of 2 mg once daily should be considered for patients who have achieved sustained control of disease activity with 4 mg once daily and are eligible for dose tapering.

Pregnancy and Breast Feeding

Olumiant is contraindicated in pregnancy, as pre-clinical data showed reduced foetal growth and malformations.

Thus,

- physicians should **advise** women of child-bearing potential to use contraception during treatment and for a week after its ending.
- Olumiant treatment should be stopped if a planned pregnancy is considered.

These points are in line with independent expert European League Against Rheumatism (EULAR) recommendations *

* Götestam Skorpen C, Hoeltzenbein M, Tincani A, 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. https://doi.org/10.1136/annrheumdis-2015-208840

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Infections

Olumiant (Baricitinib) increases the potential risk of infections.

Patients should be instructed to seek immediate medical attention if signs or symptoms suggesting infection appear.

As there is a higher incidence of infections in the elderly and in the diabetic populations in general,

- **caution** should be used when treating the elderly and patients with diabetes.
- Olumiant should only be used in patients 65 years of age and older if no suitable treatment alternatives are available.

Advise the patient that

- Olumiant use should be stopped in case of herpes zoster or any other infection that does not respond to standard treatment until the event resolves.
- they should not be immunised using live attenuated vaccines shortly before or during treatment with Olumiant.

Prescribers should screen the patients for viral hepatitis before commencing Olumiant treatment. Active tuberculosis should also be ruled out.

Prior to initiating Olumiant, it is recommended that all patients, particularly paediatric patients, be brought up to date with all immunisations in agreement with local current immunisation guidelines.

Changes in Lipid Parameters

Olumiant use is associated with hyperlipidaemia.

Prescribers should monitor the patient's lipid parameters and manage the hyperlipidaemia, if detected.

Major Adverse Cardiovascular Events

There is a potentially increased risk of MACE in patients with certain risk factors using JAK inhibitor treatment, including Olumiant.

Thus, Olumiant should only be used if no suitable treatment alternatives are available, in patients:

- 65 years of age and older,
- who are current or past long-term smokers, and
- with other cardiovascular risk factors.

Venous Thromboembolism

Olumiant increases the risk of venous thrombosis and pulmonary embolism (PE).
Olumiant(Baricitinib) should be used with caution in patients with known risk factors for deep vein thrombosis DVT/PE other than cardiovascular or malignancy risk factors.

Patients should be instructed to seek immediate medical attention if signs or symptoms of deep vein thrombosis/PE appear.

Lymphoma and Other Malignancies

Lymphoma and other malignancies have been reported in patients receiving JAK inhibitors, including Olumiant.

Thus, Olumiant should only be used if no suitable treatment alternatives are available, in patients:

- over 65 years of age,
- who are current or past long-term smokers, or
- with other malignancy risk factors (for example, current malignancy or history of malignancy).

Call for reporting

Please report any suspected adverse drug reactions, including medication errors or product complaints, to the Malta Medicines Authority. You can report by:
Filling in the Adverse Drug Reactions form available online at https://medicinesauthority.gov.mt/adrportal?l=1

and sending it to The Medicines Authority Sir Temi Zammit Buildings, Malta Life Sciences Park, San Gwann SGN 3000, Malta or via e-mail to postlicensing.medicinesauthority@gov.mt
Alternatively, you can report a suspected side effect to Pharmacovigilance Officer, Charles de Giorgio Ltd at pv@charlesdegiorgio.com or call on 99741387.

Company contact point

This communication is not intended as a complete description of the risks associated with the use of baricitinib. Please refer to the attached Summary of Product Characteristics (SmPC) for a complete description of risks.

Please contact Lilly at: 01256 315000, if you have any questions about the information in this letter or the safe and effective use of baricitinib.

To retrieve, or print the patient alert card, go to the Medicines Authority's website at : https://medicinesauthority.gov.mt/rmm

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