

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).

Baricitinib is a selective and reversible JAK1/2 inhibitor indicated for the treatment of moderate to severe atopic dermatitis (AD) in adult patients who are candidates for systemic therapy and severe alopecia areata (AA) in adult patients.

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 (MACE), and malignancy,
- aged 65 years and older, and
- with a history of chronic or recurrent infections.

A dose of 4mg 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.

Infections

Baricitinib increases the potential risk of infections.

It is important to instruct patients 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 patients that

- Olumiant use should be stopped in case of herpes zoster or any other infection that doesn't 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.

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.

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).

Changes in Lipid Parameters

Olumiant use is associated with hyperlipidaemia.

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

Venous Thromboembolism

Olumiant increases the risk of venous thrombosis and pulmonary embolism (PE). Olumiant should be used with caution in patients with known risk factors for deep vein thrombosis/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.

Call for reporting

Please report any suspected adverse drug reactions, including medication errors or product complaints, to the Malta Medicines Authorities. You can report by:

Filling in the Adverse Drug Reactions form available on line at www.medicinesauthority.gov.mt/adrportal 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 by e-mailing the Pharmacovigilance officer, Charles de Giorgio Ltd at pv@charlesdegiorgio.com or calling on 99741387.

Company contact point

This communication is not intended as a complete description of the risks associated with the use of Olumiant. 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: <http://www.medicinesauthority.gov.mt/rmm>