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

This document 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 janus kinase (JAK)1/2 inhibitor indicated for the treatment of moderate to severe atopic dermatitis (AD) in adults and paediatric patients 2 years of age and older who are candidates for systemic therapy and severe alopecia areata (AA) in adult patients and in adolescent patients 12 years of age and older.

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**.

Atopic Dermatitis and Alopecia Areata for adults:

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.

Alopecia Areata
Adolescents (12 years of age and older):

The recommended dose of baricitinib is 4 mg once daily for adolescents weighing 30 kg or more. 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.

Atopic Dermatitis
Children and adolescents (2 years of age and older):

The recommended dose of baricitinib is 4 mg once daily for patients weighing 30 kg or more. For patients weighing 10 kg to less than 30 kg, the recommended dose is 2 mg once daily. A reduction to half the dose should be considered for patients who have achieved sustained control of disease activity with the recommended dose and are eligible for dose tapering.

Infections

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.
- Baricitinib should only be used in patients 65 years of age and older if no suitable treatment alternatives are available.

Advise the patients that:

- Baricitinib 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 baricitinib.

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

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

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Changes in Lipid Parameters

Baricitinib use is associated with hyperlipidaemia.

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

Venous Thromboembolism

Baricitinib increases the risk of venous thrombosis and pulmonary embolism (PE). Baricitinib 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.

Major Adverse Cardiovascular Events

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

Thus, baricitinib 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 baricitinib.

Thus, baricitinib 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).

Pregnancy

Baricitinib 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.

Baricitinib treatment should be stopped if a planned pregnancy is considered.

Call for reporting

We remind you of the importance of reporting any suspected adverse reactions, including medication errors or product complaints, related to Olumiant® (baricitinib) to your local competent authority.

Please report to the HPRA via their Pharmacovigilance website: www.hpra.ie

When reporting please provide as much information as possible. By reporting side effects, you can help provide more information on the safety of this medicine.

Alternatively, to report adverse events or product complaints among patients taking baricitinib, please contact Lilly Ireland at: 01 664 0446.

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 for Ireland go to the HPRA website at https://www.hpra.ie/homepage/medicines/medicines-information/find-a-medicine/

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