Healthcare Professional Educational 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 janus kinase (JAK) 1/2 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.
- 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.

Infections

Olumiant 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 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.

Prior to initiating Olumiant, it is recommended that all 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.

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.

Pregnancy

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.

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).

Reporting of suspected adverse reactions

Healthcare professionals are asked to report any suspected adverse reactions. Adverse events can be reported directly to the Ministry of Health using the adverse events digital form for adverse events reporting, that is located on the Ministry of Health home page: www.health.gov.il, or by entering the link: https://sideeffects.health.gov.il

Side effects can also be reported to Eli Lilly by email: report_ilmail-ae@lilly.com

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