## Information Risk Minimization 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 JAK1/2 inhibitor indicated for the treatment of rheumatoid arthritis.

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**

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:

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

**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 baricitinib 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

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

### Changes in Lipid Parameters

In 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 long term

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| and during pregnancy and lactation. *Ann Rheum Dis*. 2016;75(5):795-810 | consequences of these changes are unknown.<br><br>**As a result of these considerations, it is important to:**<br>• Assess lipid parameters approximately 12 weeks following initiation of baricitinib therapy.<br>• Manage patients according to clinical guidelines for hyperlipidaemia thereafter.<br>• Correct elevations in LDL cholesterol with statin treatment, if necessary. |

**Call for reporting**

Please report any suspected adverse drug reactions, including medication errors or product complaints, to the Medicines Authority via ADR Reporting, website: www.medicinesauthority.gov.mt/adrportal

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset and treatment dates.

Alternatively, to report adverse events or product complaints among patients taking baricitinib, please contact Charles de Giorgio at: 0035625600500

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare Professionals are asked to report any suspected adverse reaction.

**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 Charles de Giorgio at: 0035625600500 if you have any questions about the information in this letter or the safe and effective use of baricitinib.

To receive more copies of the Patient Alert Card, please contact Charles de Giorgio at: 0035625600500