Patient Alert Card

Information for Patients about OLUMIANT® (baricitinib)

This document contains important information you should be aware of before and during treatment with Olumiant.

Keep this information with you and share it with other healthcare professionals involved in your medical care or treatment.

Your name:

Doctor's name (who prescribed Olumiant):

Doctor's phone number:

Call for reporting:

Suspected Adverse Drug Reactions (side effects) and medication errors may be reported using the Malta Medicines Authority ADR reporting form, which is available online at http://www.medicinesauthority.gov.mt/adrport al and sent by post or email to;
P: Pharmacovigilance Section at Post-

Licensing Directorate, Medicines Authority, Sir Temi Zammit Buildings, Malta Life Sciences Park, San Gwann. SGN 3000. E: postlicensing.medicinesauthority@gov.mt.

Healthcare Professionals may also report any adverse events associated with the use of Olumiant by calling 9974 1387 or by email to pv@charlesdegiorgio.com

Pregnancy

- Do not take Olumiant if you are pregnant or suspect you may be pregnant.
- Use effective contraception while taking Olumiant (and for 1 week after if you stop treatment).
- Tell your doctor immediately if you become (or wish to become) pregnant.

Infections

Olumiant may make an existing infection worse or increase the chance of you getting a new infection or increase the chance of viral reactivation. If you have diabetes or are older than 65, you may have an increased chance of getting infections. The infection can become serious if not treated. Inform your doctor immediately if you get symptoms of infection, such as:

- Fever, wounds, feeling more tired than usual, or dental problems.
- A cough that won't go away, night sweats, and weight loss. These could be symptoms of tuberculosis (an infectious disease of the lungs).
- A painful skin rash with blisters. This could be a sign of a herpes zoster infection.

Non-melanoma skin cancer

Non-melanoma skin cancer has been observed in patients taking Olumiant. If new skin lesions appear during or after therapy or if existing lesions change appearance, tell your doctor.

Blood clots

Olumiant may cause a condition in which a blood clot forms in your leg that may travel to your lungs. Inform your doctor immediately if you experience any of the following symptoms:

- Swelling or pain in one leg or arm
- Warmth or redness in one leg or arm
- Shortness of breath which is unexpected
- Rapid breathing
- Chest pain

Heart attack or stroke

Inform your doctor immediately if you experience any of the following:

- Severe chest pain or tightness (that may spread to arms, jaw, neck, back)
- Shortness of breath
- Cold sweat
- One-sided weakness in arm and/or leg
- Slurred speech