BARITOR™

Baricitinib 2 mg Tablet

PRESENTATION

Baritor™ 2 Tablet: Each film coated tablet contains Baricitinib INN 2 mg.

PHARMACOLOGY

Baricitinib is a selective and reversible inhibitor of Janus kinase (JAK)1 and JAK2. Janus kinases (JAKs) are enzymes that transduce intracellular signals from cell surface receptors for a number of cytokines and growth factors involved in haematopoiesis, inflammation and immune function. Within the intracellular signalling pathway, JAKs phosphorylate and activate signal transducers and activators of transcription (STATs), which activate gene expression within the cell. Baricitinib modulates these signalling pathways by partially inhibiting JAK1 and JAK2 enzymatic activity, thereby reducing the phosphorylation and activation of STATs.

INDICATION

Baricitinib is indicated for the treatment of adult patients with moderately to severely active Rheumatoid Arthritis who have had an inadequate response to one or more tumor necrosis factor (TNF) antagonist therapies.

DOSAGE & ADMINISTRATION

The recommended dose of Baricitinib is 2 mg once daily. It may be used as monotherapy or in combination with Methotrexate or other DMARDs. Baricitinib can be given orally with or without food.

SIDE EFFECT

The most commonly reported adverse drug reactions (ADRs) occurring in ≥ 2 % of patients treated with Baricitinib monotherapy or in combination with conventional synthetic DMARDs were increased LDL cholesterol (33.6 %), upper respiratory tract infections (14.7 %) and nausea (2.8 %).

PRECAUTION

- *Serious Infections:* Avoid use of Baricitinib in patients with an active, serious infection, including localized infections.
- *Tuberculosis:* Baricitinib should not be given to patients with active TB.

Malignancy and Lymphoproliferative Disorders: Consider the risks and benefits of Baricitinib treatment prior to initiating therapy in patients with a known malignancy other than a successfully treated non-melanoma skin cancer (NMSC) or when considering continuing Baricitinib in patients who develop a malignancy.

- *Thrombosis:* Baricitinib should be used with caution in patients who may be at increased risk of thrombosis.
- *Gastrointestinal Perforations:* Baricitinib should be used with caution in patients who may be at • • increased risk for gastrointestinal perforation.
- *Vaccinations:* Avoid use of live vaccines with Baricitinib.

CONTRAINDICATION

None

USE IN SPECIAL POPULATION

- *Pregnancy:* Baricitinib is contraindicated during pregnancy
- *Lactation:* No information is available on the presence of Baricitinib in human milk.
- *Pediatric Use:* The safety and effectiveness of Baricitinib in pediatric patients has not been established.
- *Geriatric Use:* Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection.
- *Hepatic Impairment:* No dose adjustment is necessary in patients with mild or moderate hepatic impairment.
- *Renal Impairment:* Baricitinib is not recommended for use in patients with estimated GFR of less than 60 mL/min/1.73 m^2.

DRUG INTERACTION

Strong OAT3 Inhibitors: Baricitinib exposure is increased when it is co-administered with strong OAT3 inhibitors (such as probenecid). *Other JAK Inhibitors or Biologic DMARDs:* Baricitinib has not been studied in combination with other JAK inhibitors or with biologic DMARDs.

STORAGE

Store below 30°C. Keep out of reach of children.

HOW SUPPLIED

Baritor™ 2 Tablet: Each box contains 10/20/30/40/50 tablets in blister pack.

Manufactured by

SQUARE

SQUARE

PHARMACEUTICALS LTD.

BANGLADESH