Barri® 4

Baricitinib 4 mg
Tablet

Description

Baricitinib is a selective and reversible inhibitor of Janus kinase JAK1 and JAK2. Baricitinib inhibits the activities of JAK1, JAK2, Tyrosine Kinase 2 and JAK3. 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.

Indications

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of baricitinib, in combination with remdesivir, for treatment of suspected or laboratory confirmed coronavirus disease 2019 (COVID-19) in hospitalized adults requiring supplemental oxygen, invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).

Dosage and Administration

Baricitinib is not recommended for:

- Patients who are on dialysis, have end-stage renal disease (ESRD, EGFR <15ml/min/1.73 m²), or have acute kidney injury. .
- Patients with known active tuberculosis.

Adult Patients

- The recommended dosage in adults with eGFR ≥60 mL/min/1.73 m² is 4 mg once daily for 14 days of total treatment or until hospital discharge, whichever is first.
- Dosage adjustments in patients with renal or hepatic impairment are recommended (see Renal Impairment, Hepatic Impairment).
- Dosage adjustments due to drug interactions are recommended (see Drug Interactions).
- In hospitalized patients with COVID-19, prophylaxis for venous thromboembolism (VTE) is recommended unless contraindicated.

Use in Specific Populations

Pregnancy

Baricitinib should be used during pregnancy only if the potential benefit justifies the potential risk for the mother and the fetus. Consistent with the mechanism of action, embryo-fetal toxicities including skeletal anomalies and reduced fertility have been observed in animals dosed in excess of the maximum human exposure. The limited human data on use of baricitinib in pregnant women are not sufficient to inform a drug associated risk for major birth defects or miscarriage.

Renal Impairment

There are limited data for baricitinib in patients with severe renal impairment.

- Baricitinib is not recommended for patients who are on dialysis, have ESRD, or have acute kidney injury.
- Baricitinib 4 mg should only be used in adults with eGFR 15 to <30 ml/min/1.73 m² if the potential benefit outweighs the potential risk.

Dosage Adjustments for Patients with Renal impairment (Abnormal Laboratory Values)

Laboratory Analyte	Laboratory Analyte Value	Recommendation
eGFR	30 to <60 ml/min/1.73 m²	• Adults and pediatric patients 9 years of age and older: 2 mg once daily.
eGFR	15 to <30 ml/min/1.73 m²	• Adults and pediatric patients 9 years of age and older: 1 mg once daily

eGFR = estimated glomerular filtration rate

Hepatic Impairment

Baricitinib has not been studied in patients with severe hepatic impairment. Baricitinib should only be used in patients with severe hepatic impairment if the potential benefit outweighs the potential risk. It is not known if dosage adjustment is needed in patients with severe hepatic impairment.

Administration

Baricitinib tablets are given orally once daily with or without food. For patients who are unable to swallow whole tablets, alternate administration may be considered:

- Oral dispersion
- Gastrostomy tube (G tube)
- Nasogastric tube (NG tube)

Drug Interactions

Strong OAT3 Inhibitors: Baricitinib exposure is increased when baricitinib is co-administered with strong OAT3 inhibitors (such as probenecid). In patients taking strong OAT3 inhibitors, such as probenecid, reduce the recommended dose as follows:

- If the recommended dose is 4 mg once daily, reduce dose to 2 mg once daily.
- If the recommended dose is 1 mg once daily, consider discontinuing probenecid.

Other JAK Inhibitors or biologic disease modifying anti-rheumatic drugs (DMARDs): Baricitinib has not been studied in combination with other JAK inhibitors or with biologic DMARDS (biologic treatments targeting cytokines, B-cells, or T-cells).

Warning and Precautions

- Serious infections have occurred in patients receiving baricitinib. Consider if the potential benefits outweigh the potential risks of baricitinib treatment in patients with active serious infections other than COVID-19 or chronic / recurrent infections.
- Avoid the use of baricitinib with known active tuberculosis.
- ***Thrombosis:*** In hospitalized patients with COVID-19, prophylaxis for VTE is recommended unless contraindicated. If clinical features of deep vein thrombosis/pulmonary embolism occur, patients should be evaluated promptly and treated appropriately.
- ***Abnormal Laboratory Values:*** Evaluate at baseline and thereafter according to local patient management practice. Monitor closely when treating patients with abnormal baseline and post-baseline laboratory values. Manage patients according to routine clinical guidelines.

Laboratory Analyte	Laboratory Analyte Value	Recommendation
Absolute Lymphocyte Count (ALC)	<200 cells/µL	Consider interruption until ALC is ≥200 cells/µL
Absolute Neutrophil Count (ANC)	<500 cells/µL	Consider interruption until ANC is ≥500 cells/µL
Aminotransferases	If increases in ALT or AST are observed and drug-induced liver injury (DILI) is suspected	Interrupt baricitinib until the diagnosis of DILI is excluded

ALT = alanine transaminase, AST = aspartate transaminase, DILI = drug induced liver injury

- ***Vaccinations:*** Avoid use of live vaccines with baricitinib.
- ***Hypersensitivity:*** If a serious hypersensitivity occurs, discontinue baricitinib while evaluating the potential causes of the reaction.

Serious Side Effects

Serious venous thrombosis, including pulmonary embolism, and serious infections have been observed in COVID-19 patients treated with baricitinib and are known adverse drug reactions of baricitinib.

Contraindication

There are no known contraindications for baricitinib.

Pharmaceutical Precautions

Do not store above 30° C. Keep in a dry place. Protect from light and keep out of the reach of children.

Commercial Pack

Barri® 4 Tablet: Box containing 15 tablets in 1x15's alu-alu form pack. Each film coated tablet contains Baricitinib INN 4 mg.

BEXIMCO PHARMA

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