Composition : Each film coated tablet contains Baricitinib INN 2.00 mg .

Pharmacology : Baricitinib is a selective and reversible Janus kinase 1 (JAK1) and 2 (JAK2) inhibitor. Baricitinib modulates the signaling pathway at the point of JAKs, preventing the phosphorylation and activation of STATs. The absolute bioavailability of baricitinib is approximately 80%. Plasma Protein Binding 50% and Serum Protein Binding 45%. Elimination half-life in patients with RA is approximately 12 hours. Main metabolizing enzyme CYP3A4. 75% of dose eliminated through urine and 20% of dose eliminated through feces.

Indications : Baricitinib is a Janus kinase (JAK) inhibitor indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more TNF blockers. Limitation of Use:

Not recommended for use in combination with other JAK inhibitors, biologic DMARDs, or with potent immunosuppressant's such as azathioprine and cyclosporine.

- For the treatment of COVID-19 in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or ECMO.

- It is indicated for the treatment of adult patients with severe alopecia areata.

Dosage and administration : The recommended dose of Barictinib is 2 mg once daily. It may be used as monotherapy or in combination with methotrexate or other DMARDs. It is given orally with or without food. Lymphopenia: It should be avoided the initiation or interrupt in patients with an Absolute Lymphocyte Count less than 500 cells/mm3. Alopecia Areata: 2mg once daily. Increase to 4mg once daily, if the response to treatment is not adequate. Or, as directed by the registered physician.

Administration instruction:

- Rheumatoid Arthritis and Alopecia Areata: Avoid initiation or interrupt Barinib in patients with anemia (hemoglobin<8 g/dL) or neutropenia (ANC <1000 cells/mm3).

- COVID-19: Avoid initiation or interrupt Barinib in patients with lymphopenia (ALC <200 cells/mm3) or neutropenia (ANC <500 cells/mm3).

Barinib-2

Baricitinib INN 2.00 mg Tablet

DRUG INTERNATIONAL LTD.

Contraindication : It is contraindicated in patients with known hypersensitivity to Baricitinib or any other components of this drug.

Precautions : Serious Infections: It should be avoided to use of Baricitinib in patients with active, serious infection, including localized. If a serious infection develops, interrupt Baricitinib therapy until the infection is controlled. It should not be given to patients with active tuberculosis.

- Malignancies have occurred in patients treated with Baricitinib.

- Higher rate of MACE.

- Thrombosis has occurred in patients treated with Baricitinib. Thrombosis & Gastrointestinal

Perforations: Use with caution in patients who may be at increased risk. Vaccinations: Avoid use of Baricitinib with live vaccines.

Side effects : Common side effects include: Upper respiratory tract infections (common cold, sinus infections), nausea, herpes simplex, urinary tract infection (UTI), headache, acne and herpes zoster.

Use in pregnancy and lactation: Pregnancy: This medicine may cause fetal harm. Lactation: Advise not to breastfeed.

Use in child : The safety and effectiveness of Baricitinib in pediatric patients have not been established.

Drug interactions : Strong OAT3 Inhibitors: Baricitinib exposure is increased when Baricitinib is co-administered with strong OAT3 inhibitors (such as probenecid).

Overdose : In case of an overdose, it is recommended that the patient should be monitored for signs and symptoms of adverse reactions. Patients who develop adverse reactions should receive appropriate treatment.

Storage : Store below 30°C in a dry place.
Packing : Each box contains 60's tablets in a blister pack.