TOJAK®

Tofacitinib Citrate INN Film Coated Tablet

DESCRIPTION

TOJAK® is a preparation of Tofacitinib. Tofacitinib is a Janus kinase (JAK) inhibitor. JAKs are intracellular enzymes which transmit signals arising from cytokine or growth factor-receptor interactions on the cellular membrane to influence cellular processes of hematopoiesis and immune cell function. Within the signaling pathway, JAKs phosphorylate and activate Signal Transducers and Activators of Transcription (STATs) which modulate intracellular activity including gene expression. Tofacitinib modulates the signaling pathway at the point of JAKs, preventing the phosphorylation and activation of STATs. JAK enzymes transmit cytokine signaling through pairing of JAKs (e.g., JAK1/JAK3, JAK1/JAK2, JAK1/TyK2, JAK2/JAK2). Tofacitinib inhibited the in vitro activities of JAK1/JAK2, JAK1/JAK3, and JAK2/JAK2 combinations with IC50 of 406, 56, and 1377 nM, respectively.

INDICATIONS

Tofacitinib Citrate is indicated for the treatment of moderate to severe active rheumatoid arthritis (RA) in adult patients. It can be used as monotherapy or in combination with methotrexate or other nonbiologic Disease Modifying Antirheumatic Drugs (DMARDs).

DOSAGE

The recommended dose is 5 mg orally twice daily, taken with or without food. Recommended dose in patients with moderate and severe renal impairment and moderate hepatic impairment is **TOJAK®** 5 mg once daily. Use of **TOJAK®** in patients with severe hepatic impairment is not recommended.

CONTRAINDICATIONS

Hypersensitivity to Tofacitinib Citrate. Tofacitinib is contraindicated in severe liver problems.

SIDE EFFECTS

The most commonly reported adverse reactions during the first 3 months in controlled clinical trials were headache, upper respiratory tract infections, nasopharyngitis, diarrhoea, nausea and hypertension.

PREGNANCY AND LACTATION

Pregnancy Category C. There are no adequate and well-controlled studies in pregnant women. Tofacitinib should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

It is not known whether Tofacitinib is excreted in human milk. Decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug for the mother.

WARNINGS AND PRECAUTIONS

Tofacitinib Citrate should not be initiated in patients with an active infection including localized infections. The risks and benefits of treatment should be considered prior to initiating Tofacitinib Citrate in patients with previous history or risk of tuberculosis or serious infections. Laboratory monitoring in recommended for liver enzyme and lipids. Tofacitinib Citrate should not be initiated in patients with a lymphocyte count less than 500 cells/mm3 , an absolute neutrophil count (ANC) less than 1000 cells/mm3 , or who have hemoglobin levels less than 9 g/dL. Live vaccines should not be given concurrently with Tofacitinib Citrate.

DRUG–DRUG INTERACTIONS

Tofacitinib Citrate dose should be reduced to 5 mg once daily in patients receiving potent inhibitors of cytochrome (CYP) P450 3A4 (e.g., ketoconazole). Tofacitinib Citrate dosage should be reduced to 5 mg once daily in patients receiving one or more concomitant medicinal products that result in both moderate inhibition of CYP3A4 as well as potent inhibition of CYP2C19 (e.g., fluconazole). Co-administration of Tofacitinib Citrate with potent CYP inducers (e.g., rifampicin) may result in a loss of or reduced clinical response.

PHARMACEUTICAL PRECAUTIONS

Keep away from light and wet place. Keep out of reach of children.

PACKAGING

TOJAK® tablet: Box containing 1 strip of 10 tablets. Each tablet contains Tofacitinib Citrate INN equivalent to Tofacitinib 5 mg.

SK+F
Manufactured by
ESKAYEF PHARMACEUTICALS LTD.
TONGI, GAZIPUR, BANGLADESH
REGD. TRADEMARK
PM05368 V01