Tofatin

Tofacitinib INN

Composition

Tofatin 5: Each film coated tablet contains Tofacitinib Citrate INN equivalent to Tofacitinib 5 mg.
Tofatin-XR: Each extended release tablet contains Tofacitinib Citrate INN equivalent to Tofacitinib 11 mg.

Pharmacology

Tofacitinib is believed to interfere with the activity of an enzyme called Janus kinase (JAK), which activates other cellular components which normally start the immune response in the body. By reducing the immune response Tofacitinib reduces the signs and symptoms of rheumatoid arthritis.

Indication

Tofacitinib is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to Methotrexate. It may be used as monotherapy or in combination with Methotrexate or other non-biologic Disease-Modifying Antirheumatic Drugs (DMARDs).
Tofacitinib is indicated for the treatment of adult patients with active psoriatic arthritis who have had an inadequate response or intolerance to methotrexate or other disease-modifying antirheumatic drugs (DMARDs).

Dosage and Administration

Tofatin 5 : The recommended dosage for adults is 5 mg twice daily.
Tofatin-XR : The recommended dose of Tofacitinib is 11 mg once daily.
Tofacitinib is given orally with or without food. Swallow Tofacitinib tablets whole and intact. Do not crush, split or chew.

Hepatic and renal impaired patients : The dosage is 5 mg once daily in patients with moderate or severe renal insufficiency and moderate hepatic impairment. Tofacitinib 5 mg & 11 mg should not be used in patients with severe hepatic impairment.

Dose Adjustment for Specific Disease

Dose Adjustment for Lymphopenia	
Lymphocyte count less than 500 cells/mm^3	Discontinue Tofacitinib 5 mg & 11 mg
Dose Adjustment for Neutropenia	
Absolute Neutrophil Count less than 500 cells/mm^3	Discontinue Tofacitinib 5 mg & 11 mg
Dose Adjustment for Anemia	
Greater than 2 g/dL decrease or less than 8.0 g/dL	Discontinue Tofacitinib 5 mg & 11 mg

Contraindication

None.

Adverse Reaction

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

Warning and Precaution

Tofacitinib is a medicine that affects immune system and can lower the ability of immune system to fight infections such as tuberculosis, and infections caused by bacteria, fungi or viruses that can spread throughout the body. These infections may lead to hospitalization or death. Most patients who developed these infections were taking other immunosuppressants at the same time such as Methotrexate or corticosteroids. Tofacitinib should not be used in any type of infection.

Hepatic Impairment

Use of Tofacitinib in patients with severe hepatic impairment is not recommended. No dose adjustment is required in patients with mild hepatic impairment.

Renal Impairment

Use of Tofacitinib in patients with severe renal impairment is not recommended. No dose adjustment is required in patients with mild renal impairment.

Geriatric Use

As there is a higher incidence of infections in the elderly population in general, caution should be used when treating the elderly.

Pregnancy

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.

Nursing Mother

It is not known whether Tofacitinib is excreted in human milk.

Usage in Pediatric Patient

The safety and effectiveness of Tofacitinib in pediatric patients have not been established.

Drug interaction

Tofacitinib may increase risk of adverse reactions and decrease antibody response to live vaccines; avoid concurrent use. Blood levels and effects may be increased by strong CYP3A4 inhibitors including ketoconazole or moderate CYP3A4 inhibitors/strong CYP2C19 inhibitors including Fluconazole; dose decrease is recommended. Blood levels and effectiveness may be decreased by strong CYP3A4 inducers including Rifampin; avoid concurrent use. Increase risk of immune suppression when used concurrently with other potent immunosuppressant's including Azathioprine, Cyclosporine, Tacrolimus, Antineoplastics or radiation therapy.

Storage

Keep in a cool & dry place, away from light. Keep out of reach of children.

Packaging

Tofatin 5 : Each carton contains 1x10's tablets in blister strips.
Tofatin-XR : Each carton contains 1x10's tablets in blister strips.

Manufactured by
ZISKA PHARMA **Ziska Pharmaceuticals Ltd.**
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