Tofamit™
(Tofacitinib)
Tablet

ٹوفامِٹ

COMPOSITION:
Each film coated tablet contains:
Tofacitinib citrate equivalent to
Tofacitinib ..... 5 mg.

Product Specs.: Innovator

CLINICAL PARTICULARS:
Therapeutic Indications:
- Treatment of moderate to severe active rheumatoid arthritis in adult patients with inadequate response or intolerance to one or more conventional disease modifying antirheumatic drugs.
- Treatment of active psoriatic arthritis in adult patients with inadequate response to prior therapy.
- Treatment of moderate to severe active ulcerative colitis in adult patients who have not responded adequately to conventional therapy or biologic agents.

Posology and Method of Administration:
The recommended dose is 5 mg administered orally twice daily.
Dose adjustment is required in patients with moderate renal impairment or moderate hepatic impairment.
Tofacitinib may be taken with or without food.
Treatment should be initiated and supervised by a physician experienced in the management of immune mediated inflammatory diseases.

CONTRAINDICATIONS:
- Hypersensitivity to tofacitinib or to any of the excipients.
- Severe hepatic impairment.
- Active serious infections including tuberculosis.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE:
Serious infections including opportunistic infections have been reported in patients receiving tofacitinib.
Patients should be screened for latent and active tuberculosis prior to initiation and monitored during treatment.
Malignancies including lymphomas and other cancers including non melanoma skin cancer have been observed.
An increased risk of venous thromboembolism including deep vein thrombosis and pulmonary embolism has been reported.
Major adverse cardiovascular events have been reported particularly in patients with cardiovascular risk factors.
Complete blood count liver enzymes and lipid parameters should be assessed at baseline and monitored during treatment.
Interaction with Other Medicinal Products and Other Forms of Interaction:
Strong CYP3A4 inhibitors may increase tofacitinib exposure and require dose adjustment.
Strong CYP3A4 inducers may decrease tofacitinib exposure and reduce efficacy.
Concomitant use with biologic DMARDs or potent immunosuppressants such as azathioprine or cyclosporine is not recommended.

FERTILITY PREGNANCY AND LACTATION:
Tofacitinib is not recommended during pregnancy.
Women of childbearing potential should use effective contraception during treatment.
Breastfeeding should be discontinued during treatment.

Effects on Ability to Drive and Use Machines:
Tofacitinib has no or negligible influence on the ability to drive and use machines.
Undesirable Effects:
The most commonly reported adverse reactions are upper respiratory tract infections nasopharyngitis headache and diarrhea.
Common adverse reactions include nausea vomiting hypertension anemia increased blood creatine phosphokinase and herpes zoster.
Uncommon adverse reactions include pneumonia urinary tract infections neutropenia lymphopenia elevated liver enzymes hyperlipidemia and tuberculosis.
Rare but serious adverse reactions include serious infections gastrointestinal perforation malignancies venous thromboembolism and major adverse cardiovascular events.
Laboratory abnormalities may include decreases in hemoglobin neutrophils and lymphocytes and increases in liver enzymes lipid parameters and creatine phosphokinase.

PHARMACOLOGICAL PROPERTIES:
Pharmacodynamic Properties:
Pharmacotherapeutic group Janus kinase inhibitors.
Tofacitinib inhibits Janus kinase enzymes primarily JAK1 and JAK3 with functional activity on JAK2.
This inhibition modulates signaling of multiple cytokines involved in immune cell activation differentiation and function.
The therapeutic effect is mediated through reduction of inflammatory responses in immune mediated inflammatory diseases.
Pharmacokinetic Properties:
Absorption: Tofacitinib is rapidly absorbed following oral administration with peak plasma concentrations achieved within approximately 0.5 to 1 hour.
Bioavailability: Absolute oral bioavailability is approximately 74 percent.
Distribution: Plasma protein binding is approximately 40 percent with wide tissue distribution.
Metabolism: Tofacitinib is primarily metabolized by cytochrome P450 3A4 with a minor contribution from CYP2C19.
Elimination: Clearance occurs through hepatic metabolism and renal excretion of metabolites.
Half life: The terminal half life is approximately 3 hours supporting twice daily dosing.
Special populations: Increased systemic exposure is observed in patients with renal or hepatic impairment necessitating dose adjustment.

INSTRUCTIONS:
- Store below 30ºC.
- Protect from heat, sunlight & moisture.
- Keep out of the reach of children.
- To be sold on the prescription of a registered medical practitioner only.

PRESENTATION:
Tofamit Tablet 5 mg : Pack of 1 x 10 tablets.

ہدایات:
۳۰ درجہ سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔
گرمی، دھوپ اور نمی سے بچائیں۔
بچوں کی پہنچ سے دور رکھیں۔
صرف مستند ڈاکٹر کے نسخہ پر فروخت کریں۔

Manufactured by:
Wimits Pharmaceuticals Pvt. Ltd.
Plot No. 129, Sundar Industrial Estate,
Raiwind Road, Lahore, Pakistan.

FOR FURTHER INFORMATION PLEASE CONTACT:

CCL
Marketed by:
CCL Pharmaceuticals (Pvt.) Ltd.
62 Industrial Estate, Kot Lakhpat, Lahore, Pakistan.