Tocit & Tocit XR
Tablet

DRUG INTERNATIONAL LTD.

Composition : **Tocit :** Each Film Coated Tablet Contains Tofacitinib 5 mg as Tofacitinib Citrate INN.

Tocit XR : Each Film Coated Tablet Contains Tofacitinib 11 mg as Tofacitinib Citrate INN.

Pharmacology : Tofacitinib is a Janus kinase (JAK) inhibitor. It work by preventing the phosphorylation and activation of STATs. 74% oral absorption (absolute bioavailability), with peak plasma concentrations (T_{max}) achieved in 0.5-1 hour. 70% metabolized in the liver by CYP3A4 (major) and CYP2C19 (minor). Metabolites produced are inactive. 30% renally eliminated as unchanged drug.

Indications : 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 can be used as monotherapy or in combination with methotrexate or other nonbiologic Disease Modifying Antirheumatic Drugs (DMARDs). It is also indicated for moderate to severe Psoriatic arthritis, Ulcerative colitis and Polyarticular course juvenile idiopathic arthritis.

Dosage and administration : **Recommended Dosage- Rheumatoid Arthritis :** Tocit 5 mg twice daily or Tocit XR 11 mg once daily. **Psoriatic Arthritis (in combination with nonbiologic DMARD) :** Tocit 5 mg twice daily or Tocit XR 11 mg once daily. **Ulcerative Colitis : Induction -** Tofacitinib 10mg (2 tablets of Tocit) twice daily or Tofacitinib 22mg (2 tablets of Tocit XR) once daily for 8 weeks. If needed continue Tofacitinib 10mg (2 tablets of Tocit) twice daily or Tofacitinib 22mg (2 tablets of Tocit XR) once daily for a maximum of 16 weeks. Discontinue Tofacitinib 10mg (2 tablets of Tocit) twice daily or Tofacitinib 22mg (2 tablets of Tocit XR) once daily after 16 weeks if adequate therapeutic response is not achived. **Maintenance-** Tocit 5mg twice daily or Tocit XR 11 mg once daily. The recommended dosage of tofacitinib in patients with polyarticular course juvenile idiopathic arthritis is 5mg twice daily or weight based equivalent twice daily. Or, as directed by the registered physician.

Contraindication : It is contraindicated in patients with hypersensitivity to Tofacitinib or any other components of this product.

Precautions : Use of Tofacitinib should be avoided in patients with an active infection, including localized infections. Patients with latent tuberculosis should be treated with standard antimycobacterial therapy before administering Tofacitinib.

Side effects : The most common side effects are diarrhoea, nasopharyngitis, upper respiratory tract infection, headache and hypertension.

Pregnancy and lactation : 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. There are no data on the presence of tofacitinib in human milk, the effect on a breastfed infant, or the effect on milk production. Caution should be exercised when this product is administered to a nursing woman.

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

Drug interactions : Tofacitinib exposure is increased when Tofacitinib is co-administered with potent inhibitors of cytochrome P450 CYP3A4 (e.g, ketoconazole) and CYP2C19 (e.g., fluconazole). Use of tofacitinib in combination with biologic DMARDs or potent immune suppressants such as azathioprine and cyclosporine is not recommended.

Overdose : There is no experience with overdose of tofacitinib.

Storage : Store below 30°C in a dry place.

Packing : **Tocit :** Each box contains 1 x 14's tablets in blister pack.

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