Febox
Tablet

DRUG INTERNATIONAL LTD.

Composition : **Febox-40:** Each film coated tablet contains Febuxostat INN 40mg.

Pharmacology : Febuxostat is an orally available, non-purine inhibitor of xanthine oxidase with uric acid lowering activity. Upon oral administration, Febuxostat selectively and noncompetitively inhibits the activity of xanthine oxidase, an enzyme that converts oxypurines, including hypoxanthine and xanthine, into uric acid. By inhibiting xanthine oxidase, uric acid production is reduced and serum uric acid levels are lowered.

Indications : It is a xanthine oxidase (XO) inhibitor indicated for the chronic management of hyperuricemia in adult patients with gout who have an inadequate response to a maximally titrated dose of Allopurinol, who are intolerant to Allopurinol, or for whom treatment with Allopurinol is not advisable. It is not recommended for the treatment of asymptomatic hyperuricemia.

Dosage and administration : Recommended Dose: The recommended Febuxostat dosage is 40 mg or 80 mg once daily. The recommended starting dosage of Febuxostat is 40 mg once daily. For patients who do not achieve a serum uric acid (sUA) less than 6 mg/dL after two weeks, the recommended Febuxostat dosage is 80 mg once daily. Febuxostat can be taken without regard to food or antacid use. Dose Adjustment: For Renal Impairment: No dose adjustment is necessary when administering Febuxostat in patients with mild or moderate renal impairment. The recommended dosage of Febuxostat is limited to 40 mg once daily in patients with severe renal impairment. For Hepatic Impairment: No dose adjustment is necessary in patients with mild to moderate hepatic impairment. Or, as directed by the registered physician.

Contraindication : It is contraindicated in patients being treated with Azathioprine or Mercaptopurine.

Precautions : Cardiovascular Death: Consider the risks and benefits of Febuxostat when deciding to prescribe or continue patients on Febuxostat. Physicians and patients should remain alert for the development of adverse CV event signs and symptoms. Patients should be informed about the symptoms of serious CV events and the steps to take if they occur. Gout Flares: After initiation of Febuxostat, an increase in gout flares is frequently observed. In order to prevent gout flares when Febuxostat is initiated, concurrent prophylactic treatment with an NSAID or Colchicine is recommended. Hepatic Effects: If liver injury is detected, promptly interrupt Febuxostat and assess patient for probable cause. Do not restart Febuxostat if liver injury is confirmed and no alternate etiology can be found. Serious Skin Reactions: Discontinue Febuxostat if serious skin reactions are suspected.

Side effects : The most common side effects are liver function abnormalities, nausea, arthralgia and rash.

Use in pregnancy and lactation : Pregnancy- There are no adequate and well-controlled studies in pregnant women. It should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Nursing mothers- It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Febuxostat is administered to a nursing woman.

Use in Child : Safety and effectiveness of Febuxostat in pediatric patients have not been established.

Drug interactions : Febuxostat altered the metabolism of Theophylline (a substrate of XO) in humans. Therefore, caution should be used when coadministering Febuxostat with Theophylline.

Overdose : Patients should be managed by symptomatic and supportive care if there be an overdose.

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

Packing : **Febox-40:** Each box contains 3x10's tablets in blister pack.