Urostat

Febuxostat Tablet

Presentation

Urostat Tablet : Each film coated tablet contains Febuxostat INN 80 mg.

Pharmacodynamic Properties

Febuxostat, a xanthine oxidase inhibitor, achieves its therapeutic effect by decreasing serum uric acid. Febuxostat is not expected to inhibit other enzymes involved in purine and pyrimidine synthesis and metabolism at therapeutic concentrations.

Pharmacokinetic Properties

Absorption: At least 49% Maximum plasma concentrations of Febuxostat occurred between 1 to 1.5 hours post-dose.
Distribution: The plasma protein binding of Febuxostat is approximately 99.2%
Metabolism: Febuxostat is extensively metabolized by both conjugation via uridine diphosphate glucuronosyltransferase (UGT) enzymes and oxidation via cytochrome P450 (CYP) enzymes.
Elimination: Febuxostat is eliminated by both hepatic and renal pathways. Approximately 45% of the dose was recovered in the feces. The apparent mean terminal elimination half-life (t1/2) of Febuxostat was approximately 5 to 8 hours.

Indications

Urostat is a xanthine oxidase (XO) inhibitor indicated for the chronic management of hyperuricemia in patients with gout. Febuxostat is not recommended for the treatment of asymptomatic hyperuricemia.

Dosage and Administration

For treatment of hyperuricemia in patients with gout, Urostat is recommended at 40 mg or 80 mg once daily. The recommended starting dose of Urostat is 40 mg once daily. For patients who do not achieve a serum uric acid (sUA) less than 6 mg per dL after 2 weeks with 40 mg, Urostat 80 mg is recommended. Urostat can be taken without regard to food or antacid use

Contraindications

Febuxostat is contraindicated in patients being treated with azathioprine, mercaptopurine, or theophylline.

Precautions

After initiation of Febuxostat, an increase in gout flares is frequently observed. This increase is due to reduction in serum uric acid levels resulting in mobilization of urate from tissue deposits. In order to prevent gout flares when Febuxostat is initiated, concurrent prophylactic treatment with an NSAID or colchicine is recommended.

Hepatic or Renal Function Impairment

Hepatic impairment: It should be administered cautiously.
Renal impairment: Dosage adjustments are not needed.

Drug Interactions

Inhibition of XO by Febuxostat may cause increased plasma concentrations of theophylline, mercaptopurine, azathioprine, leading to toxicity. Febuxostat does not have clinically significant interactions with colchicine, naproxen, indomethacin, hydrochlorothiazide, warfarin or desipramine. Therefore, Febuxostat may be used concomitantly with these medications.

Use in Pregnancy and Lactation

Pregnancy Category C. It is not known whether this drug is excreted in human milk. Caution should be exercised when Febuxostat is administered to a nursing woman.

Side Effects

The most common side effects of Febuxostat include:

- Liver Problems
- Nausea
- Gout Flares
- Joint Pain
- Rash

Overdosage

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

Storage Conditions

Store Febuxostat between 15°C - 30°C, Keep out of the light and all medicines out of the reach of children.

Commercial Pack

Urostat Tablet : Each box contains 2x10's or 3 x10's or 5x10's tablets in blister packs.

Manufactured by :

general **GENERAL** Pharmaceuticals Ltd.
Gazipur, Bangladesh