

Febustat[®]

Febuxostat 40 & 80 mg tablet

Presentation

Febustat[®] 40 mg tablet: Each tablet contains Febuxostat INN 40 mg.

Febustat[®] 80 mg tablet: Each tablet contains Febuxostat INN 80 mg.

Description

Febustat is FDA approved non-purine, selective inhibitor of xanthine oxidase approved for the chronic management of hyperuricemia in patients with gout. It is not recommended for asymptomatic or secondary hyperuricemia, nor is it indicated for treatment of acute gout. Febustat lowers serum uric acid levels by blocking xanthine oxidase – the enzyme responsible for uric acid production. Xanthine oxidase breaks down hypoxanthine (a natural-occurring purine derivative) to xanthine and then to uric acid.

Indications & Uses

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

Dosage and Administration

- For treatment of hyperuricemia in patients with gout, Febustat is recommended at 40 mg or 80 mg once daily.
- The recommended starting dose of Febustat 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, Febustat 80 mg is recommended.
- Febustat can be taken without regard to food or antacid use.
- No dose adjustment is necessary when administering Febustat to patients with mild to moderate renal or hepatic impairment.

Side effects

The most common side effects of Febustat are liver problems, nausea, gout flares, joint pain and rash.

Precautions

- Gout Flare: An increase in gout flares is frequently observed during initiation of anti-hyperuricemic agents, including Febustat. If a gout flare occurs during treatment, Febustat need not be discontinued. Prophylactic therapy (i.e., non-steroidal anti-inflammatory drug (NSAID) or colchicine upon initiation of treatment) may be beneficial for up to six months.
- Monitor for signs and symptoms of MI and stroke and discuss with physician.
- Liver Enzyme Elevation: Transaminase elevations have been observed in Febustat -treated patients. Monitor liver function tests periodically.

Use in Pregnancy and Lactation

Pregnancy Category C: There are no adequate and well-controlled studies in pregnant women. Febustat should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

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 Febustat is administered to a nursing woman.

Use in Children

Safety and efficacy in children below the age of 12 years have not been studied.

Contraindications

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

Drug Interactions

Concomitant administration of Febustat with azathioprine, mercaptopurine or theophylline could increase plasma concentrations of these drugs resulting in severe toxicity.

Overdosage

Febustat was studied in healthy subjects in doses up to 300 mg daily for seven days without evidence of dose-limiting toxicities.

Commercial Pack

Febustat[®] 40 mg tablet: Each box contains 3 blister strips of 10 tablets.

Febustat[®] 80 mg tablet: Each box contains 3 blister strips of 10 tablets.

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