

Goustat

Tablet

Febuxostat

Composition

Each film-coated tablet contains Febuxostat INN 40 mg.

Pharmacology

Goustat (Febuxostat) is a potent non-purine, selective inhibitor of xanthine oxidase. Goustat lowers serum uric acid levels by blocking xanthine oxidase, the enzyme responsible for uric acids production. Xanthine oxidase breaks down hypoxanthine (a natural-occurring purine derivative) to xanthine and then to uric acid.

Indications

Goustat is indicated for the chronic management of hyperuricemia in patients with gout. However, asymptomatic hyperuricemia can not be treated with Goustat.

Dosage and Administration

Route of Administration: Oral.

- Goustat is recommended at 40 mg or 80 mg once daily. The recommended starting dose of Goustat 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, Goustat 80 mg is recommended.
- Goustat can be administered without regard to food or antacid use.

OR, AS DIRECTED BY THE PHYSICIAN.

Geriatric Use

No dose adjustment is necessary in elderly patients.

Hepatic Function Impairment

No dose adjustment is necessary in patients with mild or moderate hepatic impairment. Cautions should be exercised in patients with severe hepatic impairment.

Renal Function Impairment

Dose adjustment is not required in patients with mild or moderate renal impairment.

Contraindications

Febuxostat may cause increased plasma concentration of azathioprine, mercaptopurine, or theophylline leading to toxicity. It is not recommended for coadministration with these drugs.

Warning & Precautions

- **Gout Flare:** An increase in gout flares is frequently observed during initiation of anti-hyperuricemic agents, including Febuxostat. If a gout flare occurs during treatment, Febuxostat 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.
- **Cardiovascular Events:** Monitor for signs and symptoms of MI and stroke & discuss with physician.
- **Liver Enzyme Elevation:** Transaminase elevations have been observed in Febuxostat-treated patients. Monitor liver function tests periodically.

Side Effects

Common side effects: The most common side effects of Febuxostat include: Liver problems, Nausea, Gout Flares, Arthralgia and Rash.

Rare side effects: Anxiety, skin allergic reaction & heart burn.

Adverse Effect

Long term use may increase the risk of heart disease related death.

Use in Pregnancy and Lactation

Pregnancy Category C. There are no adequate and well controlled studies in pregnant women. Febuxostat 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. Cautions should be exercised when Febuxostat is administered to a nursing woman.

Use in Children & Adolescents

Safety and effectiveness in children under 18 years of age have not been established.

Drug Interaction

With medicine: Can not be taken with theophylline, azathioprine & mercaptopurine.

With food & others: No interaction with food & others.

Overdose

There is no evidence of dose-limiting toxicities in healthy subjects taking Febuxostat up to 300 mg daily for seven days. However, Patients need to be managed by symptomatic and supportive care should there be an overdose.

Storage

Store below 30° C and in dry place, protected from light.
Keep all medicines out of reach of children.

Packing

Each box contains 2 x 10 tablets in blister strips.

*Further information is available on request



Manufactured by:

The ACME Laboratories Ltd.

Dhamrai, Dhaka, Bangladesh

For Health, Vigour and Happiness

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