Only for the use of Medical Professionals

Febus®

Febuxostat

Description

Febus®, a novel non-purine selective inhibitor of xanthine oxidase, is indicated for the management of hyperuricaemia in patients with gout. Febuxostat is advantageous over allopurinol in its potency in lowering uric acid level, eliminating the need to adjust dosing in patients with renal impairment, and solely inhibiting xanthine oxidase without interrupting other enzyme system. Febuxostat greatly expands the treatment options for refractory or allopurinol-intolerant gout.

Indications and usage

Febuxostat is indicated for treatment of chronic hyperuricaemia in conditions where urate deposition has already occurred.

Dosage and administration

Febuxostat is recommended at 40 mg or 80 mg once daily. The recommended starting dose of Febuxostat 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, Febuxostat 80 mg is recommended. Febuxostat can be administered without regard to food or antacid use. No dose adjustment is necessary when administering Febuxostat to patients with mild to moderate renal or hepatic impairment.

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 Febuxostat drug is excreted in human milk. Anima; studies have shown excretion of this substance in breast milk and impaired development of suckling pulp. A risk to suckling infant cannot be excluded. Febuxostat should not be used while breast feeding.

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 drugs (NSAIDs) or colchicines upon initiation of treatment) may be beneficial for up to six months.

Cardiovascular Events: A higher rate of cardiovascular thromboembolic events was observed in patients treated with Febuxostat than allopurinol in randomized controlled trials. A causal relationship with Febuxostat has not established. Monitor for signs and symptoms of MI and stroke.

Liver Enzyme Elevation: Transaminase elevations have been observed in Febuxostat-treated patients. Liver function tests is recommended prior to initiation of therapy with Febuxostat and periodically.

Side effects
In randomized controlled studies, adverse reactions occurring in at least 1% of Febuxostat -treated patients, and, at least 0.5% greater than placebo. Common side effects are liver function abnormalities, nausea, arthralgia, and rash.

Drug interactions
Febuxostat is a Xanthine Oxidase (XO) inhibitor. Drug interaction studies of Febuxostat with drugs that are metabolized by XO (e.g.,theophylline, mercaptopurine, azathioprine) have not been conducted. Inhibition of XO by Febuxostat may cause increased plasma concentrations of these drugs leading to toxicity.

Contraindications
Febuxostat is contraindicated to those patients who have known hypersensitivity to any component of the formulation. Febuxostat is contraindicated in patients being treated with azathioprine, mercaptopurine, or theophylline.

Overdose
Febuxostat was studied in healthy subjects in doses up to 300 mg daily for seven days without evidence of dose-limiting toxicities. No overdose of Febuxostat was reported in clinical studies. Patients should be managed by symptomatic and supportive care should there be an overdose.

Pharmaceutical precautions
Store in a cool, dry place. Protect from light.

Presentation
Febus® 40 tablet: Each tablet contains Febuxostat INN 40mg
Febus® 80 tablet: Each tablet contains Febuxostat INN 80mg

Package quantities
Febus® 40 tablet: Cartoon of 30 tablets in blister pack.
Febus® 80 tablet: Cartoon of 30 tablets in blister pack.

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