Febuglit 80 tablet

Febuxostat (80mg) Tablet

Composition:

Each tablet contains:

• Febuxostat: 80 mg

Pharmacological Class:

• Xanthine Oxidase Inhibitor

Indications:

Febuxostat (80mg) tablet is used for the management of gout and the reduction of serum uric acid levels in patients with hyperuricemia. Its main indications include:

- Chronic Gout:
 - Treatment of hyperuricemia associated with gout, to reduce the frequency of gout attacks and prevent the formation of urate crystals in the joints.
- Hyperuricemia:
 - In patients with conditions such as cancer, myeloproliferative disorders, or those undergoing chemotherapy, where hyperuricemia is a concern.
- Prevention of Uric Acid Stones:
 - Febuxostat helps reduce serum uric acid levels and may assist in preventing the formation of uric acid kidney stones.

Mechanism of Action:

Febuxostat is a selective inhibitor of xanthine oxidase, an enzyme responsible for the conversion of hypoxanthine to xanthine and xanthine to uric acid. By inhibiting this enzyme, Febuxostat reduces the production of uric acid, thereby lowering its concentration in the blood and preventing the formation of urate crystals, which are responsible for gout flare-ups and other related complications.

Dosage and Administration:

- Adults:
 - The recommended dose is 1 tablet (80 mg) once daily.

- If serum uric acid levels do not reach target levels after 2 weeks, the dose may be increased to 120 mg once daily.
- Febuxostat should be taken orally, with or without food.
- The tablet should be swallowed whole with a glass of water.
- Renal or Hepatic Impairment:
 - Use caution in patients with liver or kidney disorders. Dose adjustments may be required, and it is essential to consult with a healthcare provider for proper dosage in such cases.
- Long-term Use:
 - Febuxostat is typically used as a longterm treatment for managing gout and hyperuricemia. Regular monitoring of serum uric acid levels is recommended to assess the effectiveness of the treatment.

Warnings and Precautions:

- Cardiovascular Risk: Febuxostat has been associated with an increased risk of cardiovascular events, including heart attack and stroke, especially in patients with existing heart disease. Monitor closely if the patient has a history of heart problems.
- Severe Skin Reactions: Rare but serious allergic reactions, including rash, fever, or Stevens-Johnson syndrome, have been reported. If any of these occur, discontinue the drug and seek medical help.
- Hepatic Impairment: Monitor liver function during treatment, especially in patients with pre-existing liver conditions.
- Acute Gout Flare: When starting Febuxostat therapy, there is a risk of acute gout flare-ups. It may be beneficial to use an anti-inflammatory medication (e.g., colchicine or NSAIDs) during the initial stages of treatment to prevent flare-ups.
- Kidney Stones: In some patients, there may be an increased risk of kidney stones, especially during the initial phase of therapy. Adequate hydration should be maintained.

• Interaction with Other Medications: Febuxostat may interact with other drugs, including azathioprine, mercaptopurine, and theophylline, increasing their blood levels and the risk of toxicity. Consult a healthcare provider for proper management.

Side Effects:

Common side effects:

- Liver enzyme abnormalities
- Nausea
- Diarrhea
- Joint pain or inflammation
- Headache
- Rash

Serious but rare side effects:

- Severe allergic reactions: rash, swelling, breathing difficulties, or fever
- Heart attack or stroke: increased risk of cardiovascular events in some patients, particularly those with pre-existing cardiovascular conditions
- Hepatotoxicity: signs of liver damage, such as yellowing of the skin or eyes, dark urine, or persistent nausea
- Kidney problems: changes in urine output, kidney pain, or swelling in the feet and ankles

If any of these serious side effects occur, seek medical attention immediately.

Drug Interactions:

- Azathioprine or Mercaptopurine: Febuxostat can increase the blood concentration of these drugs, leading to toxicity. Dose adjustment of azathioprine or mercaptopurine is required when used together.
- Theophylline: Febuxostat may increase the levels of theophylline in the blood, which could increase the risk of side effects. Monitor theophylline levels and adjust the dose as needed.
- Warfarin and Anticoagulants: Use caution when using Febuxostat with blood thinners. Regular monitoring of coagulation parameters (INR) is recommended to avoid bleeding complications.
- Thiazide Diuretics: May increase the risk of uric acid crystals forming in the urine, which could lead to kidney stones.

 Cyclosporine: Co-administration with Febuxostat may increase cyclosporine levels. Adjust dosages accordingly.

Storage:

- Store at room temperature (between 20°C to 25°C).
- Keep the tablets in a dry place, away from moisture and light.
- Keep out of reach of children.

Packaging:

 Available in blister packs or bottles, typically in 30 or 60-tablet sizes.

Manufacturer:

• [Manufacturer Name]

Note:

Febuxostat is intended to lower uric acid levels in patients with gout and hyperuricemia. It is important to follow the prescribed dosage and monitor serum uric acid levels to ensure effective treatment. Do not stop taking the medication without consulting a healthcare provider, as discontinuation may lead to a recurrence of symptoms or flare-ups of gout. If you experience any side effects or unusual symptoms, contact your healthcare provider immediately for advice.

Manufactured in India for:



(An ISO 9001: 2015 Certified Co.)

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Panchkula-134113

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