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## MEDICATION GUIDE

### Febuxostat (feb ux' oh stat) (febuxostat) tablets, for oral use

Read the Medication Guide that comes with Febuxostat tablet before you start taking it and each time you get a refill. There may be new information. The Medication Guide does not take the place of talking with your doctor about your medical condition or your treatment.

#### What is the most important information that I should know about febuxostat tablet?

**Febuxostat tablet may cause serious side effects, including:**

**Heart-related deaths.**

**Call your doctor or get emergency medical help right away if you have any of the following symptoms, especially if they are new, worse, or worry you:**

- chest pain
- shortness of breath or trouble breathing
- dizziness, fainting or feeling lightheaded
- rapid or irregular heartbeat
- numbness or weakness one side of your body
- slurring of speech
- sudden blurry vision or sudden severe headache

#### What is febuxostat tablet?

Febuxostat tablet is a prescription medicine called a xanthine oxidase (XO) inhibitor used to lower blood uric acid levels in adult patients with gout when allopurinol has not worked well enough or when allopurinol is not right for you. Febuxostat tablet is not for use in people who do not have symptoms of high blood uric acid levels. It is not known if febuxostat tablet is safe and effective in children.

#### Who should not take febuxostat tablet?

**Do not take febuxostat tablet if you:**

- take azathioprine (Azasan, Imuran)
- take mercaptopurine (Purinethol, Purixan)

#### What should I tell my doctor before taking febuxostat tablet?

**Before taking febuxostat tablet tell your doctor about all of your medical conditions, including if you:**

- have taken allopurinol and what happened to you while you were taking it.
- have a history of heart disease or stroke.
- have liver or kidney problems.
- are pregnant or plan to become pregnant. It is not known if febuxostat tablet will harm your unborn baby. Talk with your doctor if you are pregnant or plan to become pregnant.
- are breastfeeding or plan to breastfeed. It is not known if febuxostat tablet passes into your breast milk. You and your doctor should decide if you should take febuxostat tablet while breastfeeding.

**Tell your doctor about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Febuxostat tablet may affect the way other medicines work, and other medicines may affect how febuxostat tablet works.

Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

#### How should I take febuxostat tablet?

- Take febuxostat tablet exactly as your doctor tells you to take it.
- Febuxostat tablet can be taken with or without food.
- Febuxostat tablet can be taken with antacids.
- Your gout may get worse (flare) when you start taking febuxostat tablet. **Do not stop taking febuxostat tablet because you have a flare.**

Your doctor may do certain tests while you take febuxostat tablet.

#### What are the possible side effects of febuxostat tablet?

**febuxostat tablet may cause serious side effects, including:**

- **Heart problems.** See “**What is the most important information I should know about febuxostat tablet?**”
- **Gout Flares.** Gout flares can happen when you start taking febuxostat tablet. Your doctor may give you other medicines to help prevent your gout flares.
- **Liver problems.** Liver problems can happen in people who take febuxostat tablet. Your doctor may do blood tests to check how well your liver is working before and during your treatment with febuxostat tablet. Tell your doctor if you get any of the following signs or symptoms of liver problems:
  - fatigue
  - loss of appetite for several days or longer
  - pain, aching, or tenderness on the right side of your stomach-area
  - dark or “tea-colored” urine
  - your skin or the white part of your eyes turns yellow (jaundice)
- **Severe skin and allergic reactions.** Serious skin and allergic reactions that may affect different parts of the body such as your liver, kidneys, heart or lungs, can happen in people who take febuxostat tablet. Call your doctor right away or get emergency medical help if you have any of the following symptoms:
  - rash
  - red and painful skin
  - severe skin blisters
  - peeling skin
  - sores around the lips, eyes or mouth
  - swollen face, lips, mouth, tongue or throat
  - flu-like symptoms

**The most common side effects of febuxostat tablet include:**

- abnormal liver function tests
- nausea
- joint pain
- rash

These are not all of the possible side effects of febuxostat tablet. **Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.**

**How should I store febuxostat tablet?**

- Store febuxostat tablet at room temperature.
- Keep febuxostat tablet out of the light.

**Keep febuxostat tablet and all medicines out of the reach of children.**

**General information about the safe and effective use of febuxostat tablet.**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use febuxostat tablet for a condition for which it was not prescribed. Do not give febuxostat tablet to other people, even if they have the same symptoms that you have. It may harm them.

You can ask your doctor or pharmacist for information about febuxostat tablet that is written for health professionals.

**What are the ingredients in febuxostat tablet?**

**Active ingredient:** febuxostat

Inactive ingredients: colloidal silicon dioxide, FD&C red #40/ allura red AC aluminum lake, FD&C yellow #5/tartrazine aluminum lake, FD&C Blue # 1/Brilliant Blue FCF Aluminum Lake, hydroxypropyl cellulose, lactose monohydrate, macrogol, microcrystalline cellulose, Polyvinyl alcohol-part hydrolyzed, magnesium stearate, sodium croscarmellose, talc, titanium dioxide.



Manufactured for:

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Manufactured by:  
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This Medication Guide has been approved by the U.S. Food and Drug Administration

Revised: September 2023