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Febuxostat

pronounced as (feb ux' oh stat)

IMPORTANT WARNING:

People who take febuxostat may be at a higher risk of heart-related death than people who take other medications for treatment of gout. Tell your doctor if you have or have ever had heart disease or a heart attack or stroke. If you experience any of the following symptoms, call your doctor immediately: chest pain, shortness of breath, rapid or irregular heartbeat, numbness or weakness on one side of your body, dizziness, fainting, slurred speech, sudden blurry vision, or sudden severe headache.

Your doctor or pharmacist will give you the manufacturer's patient information sheet (Medication Guide) when you begin treatment with febuxostat and each time you refill your prescription. Read the information carefully and ask your doctor or pharmacist if you have any questions. You can also visit the Food and Drug Administration (FDA) website (<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm> [<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm>]) or the manufacturer's website to obtain the Medication Guide.

Talk to your doctor about the risks of taking febuxostat.

Why is this medication prescribed?

Febuxostat is used to treat gout in adults who were not treated successfully with or who are not able to take allopurinol (Aloprim, Zyloprim). Gout is a type of arthritis in which uric acid, a naturally occurring substance in the body, builds up in the joints and causes sudden attacks of redness, swelling, pain, and heat in one or more joints. Febuxostat is in a class of medications called xanthine oxidase inhibitors. It works by decreasing the amount of uric acid that is made in the body. Febuxostat is used to prevent gout attacks but not to treat them once they occur.

How should this medicine be used?

Febuxostat comes as a tablet to take by mouth. It is usually taken once a day with or without food. Take febuxostat at around the same time every day. Follow the directions on your prescription label carefully,

and ask your doctor or pharmacist to explain any part you do not understand. Take febuxostat exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Your doctor may increase your dose of febuxostat after 2 weeks if a laboratory test shows that you still have too much uric acid in your blood.

It may take several months before febuxostat begins to prevent gout attacks. Febuxostat may increase the number of gout attacks during the first few months of your treatment. Your doctor may prescribe another medication such as colchicine (Colcyrs, Mitigare) or a nonsteroidal anti-inflammatory drug (NSAID) to prevent gout attacks during the first 6 months of your treatment. Continue to take febuxostat even if you have gout attacks during your early treatment.

Febuxostat controls gout but does not cure it. Continue to take febuxostat even if you feel well. Do not stop taking febuxostat without talking to your doctor.

Ask your pharmacist or doctor for a copy of the manufacturer's information for the patient.

Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before taking febuxostat,

- tell your doctor and pharmacist if you are allergic to febuxostat, allopurinol, any other medications, or any of the ingredients in febuxostat tablets. Ask your pharmacist for a list of the ingredients.
- tell your doctor if you are taking azathioprine (Azasan, Imuran) or mercaptopurine (Purinethol, Purixan). Your doctor will probably tell you not to take febuxostat if you are taking one or more of these medications.
- tell your doctor and pharmacist what other prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Be sure to mention theophylline (Elixophyllin, Theo-24, others) or cancer chemotherapy medications. Your doctor may need to change the doses of your medications or monitor you carefully for side effects.
- tell your doctor if you have or have ever had an organ transplant; cancer; Lesch-Nyhan syndrome (an inherited disease that causes high levels of uric acid in the blood, joint pain, and problems with motion and behavior); or kidney or liver disease.
- tell your doctor if you are pregnant, plan to become pregnant, or are breastfeeding. If you become pregnant while taking febuxostat, call your doctor.

What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet.

What should I do if I forget a dose?

Take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a

missed one.

What side effects can this medication cause?

Febuxostat may cause side effects. Tell your doctor if either of these symptoms is severe or does not go away:

- nausea
- joint pain

Some side effects can be serious. If you experience any of these symptoms, or those listed in the IMPORTANT WARNING section, call your doctor immediately:

- rash; skin redness or pain; blistering of lips, eyes or mouth; skin peeling; or fever and other flu-like symptoms
- swollen face, lips, mouth, tongue or throat
- yellow eyes or skin; dark urine; or pain or discomfort in right upper stomach area

Febuxostat may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>]) or by phone (1-800-332-1088).

What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature, away from light, and away from excess heat and moisture (not in the bathroom).

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org> [<http://www.upandaway.org>]

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p>]) for more information if you do not have access to a take-back program.

In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>] . If the victim has collapsed,

had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

What other information should I know?

Keep all appointments with your doctor and the laboratory. Your doctor will order certain lab tests to check your body's response to febuxostat.

Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

- Uloric[®]

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