

ABSTAT-40TM

Febuxostat 40 mg **Tablets**

Description

Febuxostat is used to lower hyperuricemia (high uric acid in the blood) in patients with gout who have been treated with allopurinol that did not work well or cannot be treated with allopurinol. This medicine is a xanthine oxidase inhibitor. It works by causing less uric acid to be produced by the body.

This medicine is available only with your doctor's prescription.

This product is available in the following dosage forms:

- Tablet

Before Using

In deciding to use a medicine, the risks of taking the medicine must be weighed against the good it will do. This is a decision you and your doctor will make. For this medicine, the following should be considered:

Allergies

Tell your doctor if you have ever had any unusual or allergic reaction to this medicine or any other medicines. Also tell your health care professional if you have any other types of allergies, such as to foods, dyes, preservatives, or animals. For non-prescription products, read the label or package ingredients carefully.

Pediatric

Appropriate studies have not been performed on the relationship of age to the effects of febuxostat in the pediatric population. Safety and efficacy have not been established.

Geriatric

Appropriate studies performed to date have not demonstrated geriatric-specific problems that would limit the usefulness of febuxostat in the elderly. However, elderly patients are more sensitive to the effects of this medicine than younger adults.

Breastfeeding

There are no adequate studies in women for determining infant risk when using this medication during breastfeeding. Weigh the potential benefits against the potential risks before taking this medication while breastfeeding.

Drug Interactions

Although certain medicines should not be used together at all, in other cases two different medicines may be used together even if an interaction might occur. In these cases, your doctor may want to change the dose, or other precautions may be necessary. When you are taking this medicine, it is especially important that your healthcare professional know if you are taking any of the medicines listed below. The following interactions have been selected on the basis of their potential significance and are not necessarily all-inclusive.

Using this medicine with any of the following medicines is not recommended. Your doctor may decide not to treat you with this medication or change some of the other medicines you take.

- Azathioprine
- Mercaptopurine

Using this medicine with any of the following medicines is usually not recommended, but may be required in some cases. If both medicines are prescribed together, your doctor may change the dose or how often you use one or both of the medicines.

- Alpelisib
- Clomipramine
- Dextroamphetamine
- Haloperidol
- Levoketoconazole
- Lisdexamfetamine
- Methotrexate
- Rosuvastatin
- Seladelpar
- Talazoparib
- Tenofovir Alafenamide
- Theophylline
- Topotecan
- Tramadol
- Ubrogepant

Other Interactions

Certain medicines should not be used at or around the time of eating food or eating certain types of food since interactions may occur. Using alcohol or tobacco with certain medicines may also cause interactions to occur. Discuss with your healthcare professional the use of your medicine with food, alcohol, or tobacco.

Other Medical Problems

The presence of other medical problems may affect the use of this medicine. Make sure you tell your doctor if you have any other medical problems, especially:

- Brain or blood vessel disease or
- Diabetes or
- Heart disease, history of—Use with caution. May increase risk for more side effects.
- Cancer or
- Lesch-Nyhan syndrome (inherited condition that causes too much uric acid in the blood) or
- Organ transplant—Use is not recommended in patients with these conditions.
- Heart attack, history of or
- Stroke, history of—Use with caution. There may be an increased risk of these conditions occurring again.
- Kidney disease, severe—Use with caution. The effects may be increased because of the slower removal of the medicine from the body.
- Liver disease, severe—Use with caution. This medicine has not been studied in patients with this condition.

Proper Use

Take this medicine only as directed by your doctor. Do not take more of it, do not take it more often, and do not take it for a longer time than your doctor ordered.

This medicine comes with a Medication Guide. Read and follow the instructions carefully. Ask your doctor if you have any questions.

You may take this medicine with or without food. It may also be taken with an antacid.

Your gout may get worse when you start using this medicine. Keep using this medicine even if this happens. Your doctor may give you other medicines (eg, colchicine or NSAID pain medicines) to help prevent these gout attacks.

Dosing

The dose of this medicine will be different for different patients. Follow your doctor's orders or the directions on the label. The following information includes only the average doses of this medicine. If your dose is different, do not change it unless your doctor tells you to do so.

The amount of medicine that you take depends on the strength of the medicine. Also, the number of doses you take each day, the time allowed between doses, and the length of time you take the medicine depend on the medical problem for which you are using the medicine.

- **For oral dosage form (tablets):**
 - **For treatment of hyperuricemia:**
 - **Adults—At first, 40 milligrams (mg) or 80 mg once a day. Your doctor may increase your dose as needed. However, the dose is usually not more than 80 mg per day.**
 - **Children—Use and dose must be determined by your doctor.**

Missed Dose

If you miss a dose of this medicine, take it as soon as possible. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not double doses.

Storage

Store the medicine in a closed container at room temperature, away from heat, moisture, and direct light.

Keep from freezing.

Keep out of the reach of children.

Do not keep outdated medicine or medicine no longer needed.

Ask your healthcare professional how you should dispose of any medicine you do not use.

Precautions

It is very important that your doctor check your progress at regular visits to make sure that this medicine is working properly. Blood and urine tests may be needed to check for unwanted effects.

Do not use azathioprine (Azasan®, Imuran®) or mercaptopurine (Purinethol®) while you are using this medicine. Using these medicines together can cause serious medical problems.

This medicine may increase your risk of having serious heart and blood vessel problems, such as unstable chest pain, heart attack, stroke, or death. Check with your doctor right away if start having chest pain, trouble with breathing, sudden or severe headache, or problems with vision, speech, or walking.

Check with your doctor right away if you have pain or tenderness in the upper stomach, pale stools, dark urine, loss of appetite, nausea, vomiting, or yellow eyes or skin. These could be symptoms of a serious liver problem.

Serious skin reactions can occur with this medicine. Check with your doctor right away if you have blistering, peeling, or loosening of the skin, red skin lesions, severe acne or a skin rash, sores or ulcers on the skin, or fever or chills with this medicine.

Do not take other medicines unless they have been discussed with your doctor. This includes prescription or nonprescription (over-the-counter [OTC]) medicines and herbal or vitamin supplements.

Side Effects

Along with its needed effects, a medicine may cause some unwanted effects. Although not all of these side effects may occur, if they do occur they may need medical attention.

Check with your doctor immediately if any of the following side effects occur:

Rare

- **Arm, back, or jaw pain**
- **black, tarry stools**
- **bloody nose**
- **blurred vision**
- **chest pain or discomfort**
- **chills**
- **cloudy urine**

- **confusion**
- **cough**
- **dark urine**
- **decreased frequency or amount of urine**
- **diarrhea**
- **difficult or labored breathing**
- **difficulty with moving**
- **dizziness**
- **dry mouth**
- **fainting**
- **fast, irregular, pounding, or racing heartbeat or pulse**
- **feeling of fullness**
- **fever**
- **gaseous abdominal or stomach pain**
- **general feeling of tiredness and weakness**
- **headache**
- **heavier menstrual periods**
- **inability to speak**
- **increase in heart rate**
- **increased thirst**
- **itching, skin rash**
- **joint pain, stiffness, or swelling**
- **large, hive-like swelling on the face, eyelids, lips, tongue, throat, hands, legs, feet, or genitals**
- **lightheadedness**
- **loss of appetite**
- **loss of bladder control**
- **muscle aching or cramping**
- **nausea**
- **nervousness**
- **pain, swelling, or redness in the joints**
- **painful or difficult urination**
- **pale skin**
- **pinpoint red spots on the skin**
- **pounding in the ears**
- **rapid breathing**
- **redness of the skin**
- **right upper abdominal or stomach pain and fullness**
- **runny nose**
- **seizures**
- **severe or sudden headache**
- **shivering**
- **slow or fast heartbeat**
- **slurred speech**
- **sore throat**
- **sores, ulcers, or white spots on the lips or in the mouth**
- **stomach fullness or pain**
- **sunken eyes**
- **sweating**
- **swelling**
- **temporary blindness**

- **thirst**
- **tightness in the chest**
- **trouble sleeping**
- **trouble swallowing**
- **unusual bleeding or bruising**
- **unusual tiredness or weakness**
- **vomiting**
- **vomiting of blood or material that looks like coffee grounds**
- **weakness in the arm or leg on one side of the body, sudden and severe**
- **weight gain**
- **wrinkled skin**
- **yellow eyes and skin**

Incidence not known

- **Blistering, peeling, or loosening of the skin**
- **diarrhea**
- **difficulty with swallowing**
- **hives**
- **hoarseness**
- **lower back or side pain**
- **muscle cramps or spasms**
- **puffiness or swelling of the eyelids or around the eyes, face, lips, or tongue**
- **red skin lesions, often with a purple center**
- **red, irritated eyes**

Some side effects may occur that usually do not need medical attention. These side effects may go away during treatment as your body adjusts to the medicine. Also, your health care professional may be able to tell you about ways to prevent or reduce some of these side effects. Check with your health care professional if any of the following side effects continue or are bothersome or if you have any questions about them:

Rare

- **Anxiety**
- **bad, unusual, or unpleasant (after) taste**
- **blistering, crusting, irritation, itching, or reddening of the skin**
- **body aches or pain**
- **breast pain**
- **bruising**
- **burning feeling in the chest or stomach**
- **burning, crawling, itching, numbness, prickling, "pins and needles", or tingling feelings**
- **change in taste**
- **changes in hair color**
- **constipation**
- **continuing ringing or buzzing or other unexplained noise in the ears**
- **cough producing mucus**
- **cracked, dry, or scaly skin**
- **decrease in smell**
- **decreased interest in sexual intercourse**
- **deep or fast breathing with dizziness**
- **depression**
- **ear congestion**
- **excess air or gas in the stomach or bowels**
- **feeling of constant movement of self or surroundings**
- **fruit-like breath odor**

- gum pain
- hair loss or thinning of the hair
- hearing loss
- heartburn
- inability to have or keep an erection
- inability to move the arms and legs
- increased or decreased appetite
- increased sensitivity of the skin to sunlight
- increased sweating
- increased urination
- irritability
- large, flat, blue, or purplish patches in the skin
- loss in sexual ability, desire, drive, or performance
- loss of consciousness
- loss of voice
- muscle or bone pain or stiffness
- muscle spasm, tightness, or weakness
- muscle twitching
- nasal congestion
- numbness of the feet, hands, and around the mouth
- painful blisters on the trunk of the body
- pains in the stomach, side, or abdomen, possibly radiating to the back
- sensation of spinning
- severe or continuing stomach pain
- severe sunburn
- shakiness in the legs, arms, hands, or feet
- skin rash, encrusted, scaly, and oozing
- sleepiness or unusual drowsiness
- small red or purple spots on the skin
- sneezing
- stomach discomfort, upset, or pain
- sudden numbness and weakness in the arms and legs
- sweating
- swelling of the breasts or breast soreness in both females and males
- throat irritation
- trembling or shaking of the hands or feet
- trouble sleeping
- unexplained weight loss
- unusual drowsiness, dullness, or feeling of sluggishness
- weight loss

Incidence not known

- Aggressive thoughts
- false beliefs that cannot be changed by facts
- seeing, hearing, or feeling things that are not there

Other side effects not listed may also occur in some patients. If you notice any other effects, check with your healthcare professional.