

CONSUMER MEDICINE INFORMATION

FEBUXOSTAT (TEVA)

Febuxostat hemihydrate 80 mg & 120 mg tablets

What is in this leaflet

Please read this leaflet carefully before you start using Febuxostat (Teva).

This leaflet answers some common questions about Febuxostat (Teva). It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Febuxostat (Teva) against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Febuxostat (Teva) is used for

Febuxostat (Teva) is used to treat gout, which is associated with an excess of a chemical called uric acid (urate) in the body. In some people, the amount of uric acid builds up in the blood and may become too high to remain soluble. When this happens, urate crystals may form in and around the joints and kidneys. These crystals can cause sudden, severe pain, redness, warmth and swelling in a joint (known as a gout attack). Left untreated, larger deposits called tophi may form in and around joints. These tophi may cause joint and bone damage.

Febuxostat (Teva) works by reducing uric acid levels. Keeping uric acid levels low by taking Febuxostat (Teva) tablets once every day stops crystals building up, and over time it reduces symptoms. Keeping uric acid levels sufficiently low for a long enough period can also shrink tophi.

Febuxostat (Teva) 80 mg tablets are also used to treat and prevent high blood levels of uric acid that may occur when you start to receive chemotherapy for blood cancers.

When chemotherapy is given, cancer cells are destroyed, and uric acid levels increase in the blood accordingly, unless the formation of uric acid is prevented.

Your doctor may have prescribed Febuxostat (Teva) for another reason.

Ask your doctor if you have any questions about why Febuxostat (Teva) has been prescribed for you.

Before you take Febuxostat (Teva)

When you must not take it

Do not take Febuxostat (Teva) if

- you have ever had an allergy to febuxostat or any of the ingredients listed at the end of this leaflet
Symptoms of an allergic reaction may include: rash, itching or hives on the skin; shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body.
- you are having an acute attack of gout and are not already taking Febuxostat (Teva)

Your doctor will wait until the symptoms of the acute attack of gout have subsided before starting you on Febuxostat (Teva).

Febuxostat (Teva) is used for prevention of gout not for an acute attack. However, if a gout flare occurs during febuxostat treatment, it should not be discontinued. The gout flare should be managed concurrently as appropriate for the individual patient. Continuous treatment with febuxostat decreases frequency and intensity of gout flares.

Do not take Febuxostat (Teva) if you are pregnant or intend to become pregnant.

As it is not known if Febuxostat (Teva) may harm your unborn child, it is not recommended for use during pregnancy.

Do not take Febuxostat (Teva) if you are breast-feeding or plan to breast-feed.

It is not known if Febuxostat (Teva) passes into breast milk.

Do not give Febuxostat (Teva) to children under 18 years.

The safety and effectiveness of Febuxostat (Teva) in children under 18 years have not been established.

Do not take Febuxostat (Teva) after the expiry date printed on the pack.

If you take this medicine after the expiry date has passed, it may not work.

Do not take Febuxostat (Teva) if the packaging is torn or shows signs of tampering.

If you are not sure whether you should start taking Febuxostat (Teva), talk to your doctor.

Before you take it

Tell your doctor if you have:

- heart problems
- kidney problems
- serious allergic reaction to allopurinol (a medication used for treatment of gout)
- liver problems
- high uric acid levels as a result of Lesch-Nyhan syndrome
- thyroid problems
- lactose intolerance

If you have not told your doctor about any of the above, tell them before you start taking Febuxostat (Teva).

Tell your doctor if you have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes

Tell your doctor if you are pregnant or intend to become pregnant.

Your doctor will discuss the possible risks and benefits of using Febuxostat (Teva) during pregnancy.

Tell your doctor if you are breast-feeding or plan to breast-feed.

Your doctor will discuss the possible risks and benefits of taking Febuxostat (Teva) during breastfeeding.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking Febuxostat (Teva).

Some medicines may interfere with Febuxostat (Teva). These include:

- mercaptopurine (used to treat cancer)
- azathioprine (used to reduce immune response)
- theophylline

These medicines may be affected by Febuxostat (Teva), or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Febuxostat (Teva).

How to take Febuxostat (Teva)

Follow the directions given to you by your doctor and pharmacist. These directions may differ from the information contained in this leaflet.

How much to take

The usual dose is one tablet daily.

For the treatment of gout, Febuxostat (Teva) 80 mg and 120 mg tablets are available. Your doctor will have prescribed the strength most suitable for you.

For the prevention and treatment of high uric acid levels in patients undergoing cancer chemotherapy, Febuxostat (Teva) 120 mg tablets are available. Start taking Febuxostat (Teva) two days before chemotherapy and continue its use according to your doctor's advice. Usually treatment is short term.

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

How to take it

Febuxostat (Teva) should be taken by mouth, with or without food.

When to take it

Take Febuxostat (Teva) tablets at about the same time each day unless your tells you otherwise.

Taking your tablets at the same time each day will have the best effect. It will also help you remember when to take the tablets.

If you are taking Febuxostat (Teva) once a day, this is best in the morning for example, at breakfast time (if appropriate).

It does not matter if you take Febuxostat (Teva) tablets before or after food.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints. The back of the blister pack is marked with the days of the week to help you check that you have taken a dose each day.

How long to take it

Continue to take Febuxostat (Teva) every day even when you are not experiencing gout flare attack.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

While you are taking Febuxostat (Teva)

Things you must do

Stop taking Febuxostat (Teva) and contact your doctor immediately if you develop any of the following:

- Rash including severe forms (e.g. blisters, nodules, itchy, exfoliative rash)
- Itchiness
- Swelling of limbs and face
- Difficulties in breathing
- Serious life threatening allergic conditions with cardiac and circulatory arrest.

These may be the first signs of a serious allergic reaction to Febuxostat (Teva). You may need urgent medical attention.

Your doctor might decide to permanently stop treatment with Febuxostat (Teva).

If you are already taking Febuxostat (Teva) when an acute gout attack occurs, tell your doctor immediately. Your doctor may prescribe other medicines to treat the symptoms of flares.

It is important to keep taking Febuxostat (Teva) even if you have a flare, as Febuxostat (Teva) is still working to lower uric acid. Over time, gout flares will occur less often and be less painful if you keep taking Febuxostat (Teva) every day.

In patients with very high urate levels (e.g. those undergoing cancer chemotherapy), treatment with uric acid-lowering medicines could lead to the build-up of xanthine in the urinary tract, with possible stones, even though this has not been observed in patients being treated with Febuxostat (Teva) for Tumor Lysis Syndrome.

If you become pregnant while taking Febuxostat (Teva), tell your doctor.

Tell any other doctors, dentists, and pharmacists who are treating you that you are taking Febuxostat (Teva).

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking Febuxostat (Teva).

Things you must not do

Do not give Febuxostat (Teva) to anyone else, even if they have the same condition as you.

Do not take Febuxostat (Teva) to treat any other complaints unless your doctor tells you to.

Do not stop taking Febuxostat (Teva), or lower the dosage, without checking with your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how Febuxostat (Teva) affects you.

Febuxostat (Teva) may cause sleepiness, dizziness, blurred vision and numbness or tingling in some people. Make sure you know how you react to Febuxostat (Teva) before you drive a car, operate machinery, or do anything else that could be dangerous. **If this occurs do not drive.**

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Febuxostat (Teva).

Febuxostat (Teva) helps most people with gout, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- headache
- nausea
- diarrhoea
- rash
- increase in gout symptoms
- localised swelling (oedema)

These are mild side effects of Febuxostat (Teva).

If any of the following happen, tell your doctor or pharmacist immediately or go to Accident and Emergency at your nearest hospital:

- sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing (anaphylaxis)
- severe skin reaction starting with painful red areas, then large blisters and ending with peeling of layers of skin
- pinkish, itchy swellings on the skin
- fever

These are serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.

Other side effects not listed above may occur in some patients. Tell your doctor if you notice anything that is making you feel unwell.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much Febuxostat (Teva).

Do this even if there are no signs of discomfort or poisoning.

Storage conditions

Storage

Keep your Febuxostat (Teva) tablets in the pack until it is time to take them.

Store below 25°C and out of reach of children.

Do not store Febuxostat (Teva), or any other medicine, in the bathroom or near a sink.

Disposal

If your doctor tells you to stop taking Febuxostat (Teva) or if the tablets have passed the expiry date, ask your pharmacist what to do with the remaining medicine.

Product Description

What Febuxostat (Teva) tablets look like

80 mg tablets: Capsule-shaped, biconvex, yellow coloured tablet with "A275" printed on one side and 80 on the other side.

120 mg tablets: Capsule-shaped, biconvex, yellow coloured tablet with "A265" printed on one side and 120 on the other side.

Ingredients

Tablet Core

Microcrystalline cellulose, lactose monohydrate, hydroxypropyl cellulose, croscarmellose sodium, colloidal anhydrous silica, magnesium stearate.

Tablet Coating

Polyvinyl alcohol, macrogol 3350, talc, titanium dioxide, iron oxide yellow.

Who supplies this medicine

Distributed in New Zealand by:

Teva Pharma (New Zealand) Limited

PO Box 128 244

Remuera

Auckland 1541

Telephone: 0800 800 097

Date of information

30 April 2020