

PATIENT INFORMATION ON

FEBUXOSTAT

(Brand names: Adenuric)

This information sheet has been produced by the Australian Rheumatology Association to help you understand the medicine that has been prescribed for you. It includes important information about:

- **how you should take your medicine**
- **what are the possible side effects**
- **what tests you may have to monitor your condition and to detect unwanted effects, and**
- **other precautions you should take.**

Please read it carefully and discuss it with your doctor.

Important things to remember

- Once you are prescribed febuxostat it is very important that you do not stop taking it unless advised by your doctor or unless side effects develop. If febuxostat treatment is stopped there is a high risk that your gout may worsen.
- You should continue to take it even if you do not have symptoms.
- You should also continue to take febuxostat during an attack of gout.
- There is an increased risk of death when taking febuxostat compared with taking allopurinol for gout in patients with heart disease.

For more information about GOUT see the Arthritis Australia website:
www.arthritisaustralia.com.au/index.php/arthritisminformation/information-sheets.html.

What is febuxostat?

Febuxostat (brand name: Adenuric) is a medicine used to treat gout, which is a type of arthritis caused by a build up of uric acid crystals in the joints. Cells produce uric acid normally. In gout the body does not flush it out fast enough.

Febuxostat works by reducing the amount of uric acid made by cells. This helps prevent uric acid crystals building up in the joints and therefore helps prevent joints becoming swollen and painful.

What benefit can you expect from your treatment?

Febuxostat is taken on a long-term basis to prevent attacks of gout. Taking febuxostat regularly each day will also help to prevent permanent damage to the joints and bone. It does not treat the pain or inflammation of an 'attack' of gout and it is not normally started during a sudden attack.

Febuxostat does not work straight away. It may take several weeks to reduce the level of uric acid so you may continue to have gout attacks for some time.

Sometimes starting febuxostat or increasing the dose can actually cause an attack of gout. This does not mean the medicine is not working, so keep taking it during such attacks together with any other medicine your doctor may recommend to manage pain.

To reduce the risk of a gout attack, medicines such as colchicine or anti-inflammatory drugs may be recommended before or at the same time febuxostat is started. Your doctor will

advise you about how these medicines should be taken.

What happens if you have a gout attack?

Febuxostat is not a pain reliever. You should continue to take febuxostat during an attack, but your doctor will also recommend medicines to treat pain and inflammation. These may include paracetamol, colchicine, anti-inflammatory drugs such as naproxen (Naprosyn), ibuprofen (Brufen/Nurofen), indomethacin (Indocid) or steroids such as prednisolone.

It is a good idea to plan with your doctor what to do if a gout attack occurs and to have symptom controlling medicine ready to use if needed. It is also important that you tell your doctor if your condition persists or worsens.

How is febuxostat taken?

Febuxostat is taken by mouth as a tablet. It is usually taken once a day. You should take your febuxostat at about the same time each day.

It does not matter if you take febuxostat before or after food. It should be taken with a full glass of water.

For greatest benefit, febuxostat should be taken regularly. If you forget to take a dose, take it as soon as you remember, then go back to taking it as you would normally. There is no need to double the dose at the next scheduled dose time.

What is the dosage?

Febuxostat tablets are available in one strength of 80mg. Treatment may start with a small dose of 40mg (half a tablet) once a day. Over time your doctor may increase your dose to 80mg (one tablet) daily. Higher doses are used in some cases.

Can other medicines be taken with febuxostat?

Febuxostat may be taken in combination with other arthritis medicines, including:

- steroid medicines such as prednisolone or cortisone injections into the joint

- anti-inflammatory medicines (NSAIDs) such as naproxen (Naprosyn) or ibuprofen (Brufen/Nurofen)
- colchicine (Colgout)
- simple pain relieving medicines such as paracetamol.

There are separate information sheets for the medicines mentioned above.

How long is the treatment continued?

Treatment with febuxostat may be continued indefinitely as long as it is effective and as long as no serious side effects occur.

If you stop febuxostat treatment suddenly there is a high risk that your gout may worsen. It is very important not to stop your treatment unless advised by your doctor or unless side effects develop.

Are there any side effects?

Most people do not experience side effects from febuxostat. A clinical study published in 2018 compared approximately 3000 people taking febuxostat with the same number of people taking allopurinol to treat gout. All patients had heart disease as well as gout. The risk of dying was about 30% higher in people taking febuxostat. Tell your doctor if you are concerned about any possible side effects.

Most common possible side effects

- The most common side effects are *headache, nausea or diarrhoea*. They are usually mild and short-lasting. Febuxostat may also cause an increase in gout symptoms in the first few months.

Less common or rare possible side effects

There are some very rare but potentially serious side effects with febuxostat.

- *Skin problems*: Febuxostat can cause a skin rash. Very rarely, an allergic reaction to febuxostat can occur. Signs of an allergic reaction include a severe skin rash with itching or hives, swelling of the face, lips, tongue or other parts of the body, and shortness of breath or trouble

breathing. You must seek medical attention straight away. Mouth ulceration can occur.

- *Liver:* Febuxostat can cause changes to liver function. Your doctor may do blood tests to check if this occurs. The dose of febuxostat may need to be reduced or it may need to be stopped if problems occur. Contact your doctor immediately if you notice yellowing of the skin and/or whites of the eyes.
- *Other rare side effects:* Changes in appetite, dizziness, taste disturbances, high blood pressure, heart palpitations and pins and needles.

Long term side effects

Febuxostat can be taken for long periods to manage gout. Very rarely, febuxostat may alter thyroid function when used long term. Your doctor will monitor for this with blood tests.

What precautions are necessary?

Blood tests

- You may need to have blood tests during the first few months of treatment depending on what other medicines you are taking and depending on your other health concerns. The uric acid level in your blood will be checked to make sure the medicine is working.
- It is important to see your general practitioner (GP) regularly as they have an important role in monitoring your condition.

Use with other medicines

- Febuxostat can interact with some other medicines. You should tell your doctor (including your general practitioner, rheumatologist and others) about all medicines you are taking or plan to take. This includes medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also mention your treatment when you see other health professionals.

- Febuxostat increases the blood levels of the immune suppressing medications azathioprine (Imuran) and mercaptopurine (Puri Nethol). Taking febuxostat with either of these medications can be very dangerous. You must tell your doctor if you are taking or are advised to take either of these medications. If either of these medications is taken with febuxostat you may need a different dose of your medicine.
- Other medicines that may interfere with febuxostat include: theophylline, rosiglitazone and phenytoin.
- Aspirin can be used safely in the low doses taken for prevention of heart attack and stroke. You should avoid taking aspirin in all other circumstances as at higher doses it can raise the uric acid level.
- Febuxostat can be taken safely with anti-inflammatory drugs (NSAIDs) provided your kidney function is normal.
- The simple pain reliever paracetamol and combined medicines such as Panadeine and Panadeine Forte can be used while taking allopurinol provided you take them as directed.

Use with alcohol

- Alcohol can trigger an attack of gout. When taking febuxostat, keep your alcohol intake to a minimum i.e. 1 to 2 standard drinks, once or twice a week. Drinking more than 4 standard drinks on one occasion, even if infrequently, is strongly discouraged. In some cases total abstinence from alcohol is recommended. Check with your doctor about your situation.
- In addition to alcohol, other things that may trigger an acute gout attack include dehydration, diuretics (fluid tablets) and stopping febuxostat treatment.

Use in pregnancy and when breastfeeding

- You should not take febuxostat if you are pregnant. It is not known whether febuxostat causes birth defects.
- If you are pregnant or are considering having a child you should discuss this with your doctor before beginning this medication.
- You should not breast-feed if you are taking febuxostat. It is not known if

febuxostat passes into breast milk and there is a possibility your baby may be affected.

How to store febuxostat

- Store your febuxostat tablets in a cool, dry place, away from direct heat and light.
- Keep all medicines out of reach of children.

Questions?

If you have any questions or concerns write them down and discuss them with your doctor.

Your doctor's contact details

If you are taking febuxostat you should see your doctor regularly to make sure the treatment is working and to minimise any possible side effects.

The information in this sheet has been obtained from various sources and has been reviewed by the Australian Rheumatology Association. It is intended as an educational aid and does not cover all possible uses, actions, precautions, side effects, or interactions of the medicines mentioned. This information is not intended as medical advice for individual problems nor for making an individual assessment of the risks and benefits of taking a particular medicine. It can be reproduced in its entirety but cannot be altered without permission from the ARA. The NHMRC publication: *How to present the evidence for consumers: preparation of consumer publications* (2000) was used as a guide in developing this publication.