

ADENURIC[®] Tablets

febuxostat 80 mg and 120 mg tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about ADENURIC[®] Tablets.

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 taking ADENURIC[®]

Tablets against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What ADENURIC[®] Tablets are used for

ADENURIC[®] Tablets contain the active substance febuxostat and are 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.

ADENURIC[®] Tablets work by reducing uric acid levels. Keeping uric acid levels low by taking ADENURIC[®] 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.

ADENURIC 120 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.

Before you take ADENURIC[®] Tablets

When you must not take it

Do not take ADENURIC[®] Tablets if:

- you have ever had an allergy to febuxostat or any of the ingredients listed at the end of this leaflet
- you are having an acute attack of gout and are not already taking ADENURIC[®] Tablets

Your doctor will wait until the symptoms of the acute attack of gout have subsided before starting you on ADENURIC[®] Tablets.

ADENURIC[®] Tablets are 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 ADENURIC[®] Tablets if you are pregnant or intend to become pregnant.

As it is not known if ADENURIC[®] Tablets may harm your unborn child, it is not recommended for use during pregnancy.

Do not take ADENURIC[®] Tablets if you are breast-feeding or plan to breast-feed.

It is not known if ADENURIC[®] Tablets pass into breast milk.

Do not give ADENURIC[®] Tablets to children under 18 years.

The safety and effectiveness of ADENURIC[®] Tablets in children under 18 years have not been established.

Do not take ADENURIC[®] Tablets 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 ADENURIC[®] Tablets if the packaging is torn or shows signs of tampering.

If you are not sure whether you should start taking ADENURIC[®] Tablets, talk to your doctor.

Before you start to take it

Tell your doctor if you have or have had any medical conditions, especially the following:

- heart problems or a stroke
- 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 ADENURIC[®] Tablets

Your doctor will consider your cardiovascular risk factors before prescribing ADENURIC[®].

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 ADENURIC[®] Tablets 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 ADENURIC[®] Tablets during breastfeeding.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and ADENURIC[®] tablets may interfere with each other. These include:

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

These medicines may be affected by ADENURIC[®] Tablets, 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 will advise you.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while taking ADENURIC[®] Tablets.

How to take ADENURIC[®] Tablets

Take ADENURIC[®] Tablets only when prescribed by your doctor.

How much to take

Your doctor will tell you how many tablets you will need to take each day. This depends on your condition and whether or not you are taking any other medicines.

The usual dose is one tablet daily. 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.

Gout

ADENURIC is available as either an 80 mg tablet or a 120 mg tablet. Your doctor will have prescribed the strength most suitable for you.

Prevention and treatment of high uric acid levels in patients undergoing cancer chemotherapy

ADENURIC is available as a 120 mg tablet.

Start taking ADENURIC 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 box, ask your doctor or pharmacist for help.

How to take it

ADENURIC[®] Tablet should be taken by mouth with or without food.

When to take it

Take ADENURIC[®] Tablets at about the same time each day unless your doctor 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 ADENURIC[®] Tablets once a day, this is best in the morning, for example, at breakfast time (if appropriate).

It does not matter if you take ADENURIC[®] 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 ADENURIC[®] Tablets every day even when you are not experiencing gout flare attack.

If you take too much (overdose)

Immediately telephone your doctor or pharmacist or the Poisons Information Centre (Australia telephone 13 11 26, New Zealand telephone 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 ADENURIC[®] Tablets. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using ADENURIC[®] Tablets

Things you must do

Stop taking ADENURIC[®] Tablets and immediately contact your doctor or go to Accident and Emergency at your nearest hospital if you develop any of the following of the following allergy symptoms. Sometimes a serious but rare allergic reaction may follow:

- Rash including severe forms (e.g. blisters, nodules, itchy, exfoliative rash)
- Shedding of the skin and inner surfaces of body cavities (e.g. mouth and genitals, painful ulcers in the mouth and/or genital areas, accompanied by fever, sore throat and fatigue)
- Enlarged lymph nodes
- Generalised skin rashes
- 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 ADENURIC[®] Tablets. You may need urgent medical attention.

Your doctor might decide to permanently stop treatment with ADENURIC[®] Tablets.

If you are already taking ADENURIC[®] Tablets 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 ADENURIC[®] Tablets even if you have a flare, as ADENURIC[®] is still working to lower uric acid. Over time, gout flares will occur less often and be less painful if you keep taking ADENURIC[®] Tablets 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 ADENURIC[®] for Tumor Lysis Syndrome.

If you become pregnant while taking ADENURIC[®] Tablets, tell your doctor.

Tell any other doctors, dentists, and pharmacists who are treating you that you are taking ADENURIC[®] Tablets.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking ADENURIC[®] Tablets.

Things you must not do

Do not give ADENURIC[®] Tablets to anyone else, even if they have the same condition as you.

Do not take ADENURIC[®] Tablets to treat any other complaints unless your doctor tells you to.

Do not stop taking ADENURIC[®] Tablets, or lower the dosage, without checking with your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how ADENURIC[®] Tablets affects you.

ADENURIC[®] Tablets may cause sleepiness, dizziness, blurred vision and numbness or tingling in some people. Make sure you know how you react to ADENURIC[®] Tablets 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 ADENURIC[®] Tablets.

ADENURIC[®] Tablets 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 ADENURIC[®] Tablets.

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

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

Some of these side effects can only be found when your doctor does tests from time to time to check your progress.

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

You may not experience any of them.

After using ADENURIC[®] Tablets

Storage

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack they will not keep well.

Keep your tablets in a cool dry place away from light where the temperature stays below 30°C.

Do not store ADENURIC[®] Tablets or any other medicine in the bathroom or near a sink.

Do not leave it in the car on hot days or on window sills.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor or pharmacist tells you to stop taking ADENURIC[®] Tablets or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

ADENURIC[®] Tablets are available in two strengths of tablets: 80 mg and 120 mg

80 mg tablets - pale yellow to yellow capsule shaped tablets marked with '80' on one side.

120 mg tablets - pale yellow to yellow capsule shaped tablets marked with '120' on one side.

ADENURIC[®] Tablets are available in blister packs of 28 tablets.

Ingredients

Active ingredients:

- febuxostat

Other ingredients:

- lactose
- cellulose-microcrystalline
- magnesium stearate,
- hydroxypropylcellulose,
- croscarmellose sodium
- silicon dioxide.

Core tablets are coated with Opadry II Yellow, 85F42129 containing:

- polyvinyl alcohol
- titanium dioxide
- macrogol 3350
- talc-purified
- iron oxide yellow.

ADENURIC[®] Tablets do not contain sucrose, gluten, tartrazine or any other azo dyes.

Supplier

New Zealand

A. Menarini New Zealand Pty Ltd
4 Whetu Place,
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Phone: 0800 102 349

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For the most up to date version of this leaflet, please go to www.medsafe.govt.nz.

