

# ADENURIC®

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## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

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**WARNING:** Important safety information is provided in a boxed warning in the [full CMI](#). Read before using this medicine.

## 1. Why am I taking ADENURIC?

ADENURIC contains the active ingredient febuxostat. ADENURIC is used in the treatment of gout, a type of arthritis associated with high uric acid levels. For more information, see Section [1. Why am I taking ADENURIC?](#) in the full CMI.

## 2. What should I know before I take ADENURIC?

Do not use if you have ever had an allergic reaction to febuxostat or any of the ingredients listed at the end of the CMI. Talk to your doctor if you have any other medical conditions, take any other medicines, are pregnant, plan to become pregnant or are breastfeeding.

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For more information, see Section [2. What should I know before I take ADENURIC?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with ADENURIC and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I take ADENURIC?

- The usual dose is 40 mg (half a tablet) or 80 mg (1 whole tablet) once daily with a full glass of water. This depends on your condition and whether or not you are taking any other medicines.
- This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

More instructions can be found in Section [4. How do I take ADENURIC?](#) in the full CMI.

### 5. What should I know while taking ADENURIC?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are taking ADENURIC.</li></ul>
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	<ul style="list-style-type: none"> <li>• Stop taking ADENURIC and contact your doctor if you experience any allergy symptoms listed in Section 5 in the full CMI. Notify your doctor of any side effects or symptoms that worry you.</li> <li>• Keep your doctor's appointments so your progress can be monitored.</li> </ul>
<p><b>Things you should not do</b></p>	<ul style="list-style-type: none"> <li>• Do not stop taking ADENURIC or lower the dosage without checking with your doctor.</li> <li>• Do not stop taking ADENURIC if you have a gout flare while you are taking ADENURIC.</li> <li>• Do not initiate ADENURIC if you are having an acute attack of gout and are not taking ADENURIC already.</li> </ul>
<p><b>Driving or using machines</b></p>	<ul style="list-style-type: none"> <li>• Do not drive or operate machinery as ADENURIC may cause drowsiness, dizziness,</li> </ul>

	pins and needles, and blurred vision in some people.
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>• Keep your tablets in the pack until it is time to take them. Store your medicine in a cool dry place below 30°C. Keep your medicine where children cannot reach it.</li> </ul>

For more information, see Section [5. What should I know while taking ADENURIC?](#) in the full CMI.

## 6. Are there any side effects?

The most common side effects of ADENURIC are gout flares, liver function abnormalities, diarrhoea, headaches, nausea, dizziness, shortness of breath, rash, itching, joint or muscle pain, pain in extremity, localised swelling and fatigue. Call your doctor immediately or go to the Emergency Department at your nearest hospital if you experience chest pain, shortness of breath, dizziness or feeling lightheaded, rapid or irregular heartbeat, numbness or weakness on one side of your body, slurring of speech, sudden blurry vision, sudden severe headache, sudden rash, itching or hives on the skin, swelling of the face, lips, tongue or other part of the body, abdominal pain or painful red areas, large blisters and peeling of layers of skin, fever, vomiting, or muscle pain, tenderness or weakness.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

## **WARNING**

Serious heart-related side effects, including heart-related death have been observed in a long term clinical study with ADENURIC in patients with pre-existing serious heart conditions. Tell your doctor if you have or have had heart disease, heart failure, a heart attack or a stroke. Seek emergency medical help right away if you have any of the following symptoms: chest pain, shortness of breath, trouble breathing, dizziness, fainting, feeling lightheaded, rapid or irregular heartbeat, numbness or weakness in one side of your body, slurring of speech, sudden blurry vision or sudden severe headache.

## **ADENURIC®**

**Active ingredient(s):** febuxostat

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### **Consumer Medicine Information (CMI)**

This leaflet provides important information about taking ADENURIC. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking ADENURIC.**

**Where to find information in this leaflet:**

- [1. Why am I taking ADENURIC?](#)
- [2. What should I know before I take ADENURIC?](#)
- [3. What if I am taking other medicines?](#)

[4. How do I take ADENURIC?](#)

[5. What should I know while taking ADENURIC?](#)

[6. Are there any side effects?](#)

[7. Product details](#)

## **1. Why am I taking ADENURIC?**

**ADENURIC contains the active ingredient febuxostat.** ADENURIC belongs to a class of drugs called xanthine oxidase inhibitors. It works by reducing the formation and accumulation of uric acid in the blood to reduce crystal formation.

ADENURIC is used in the treatment of long-standing high uric acid levels in the blood. High levels of uric acid in the blood leads to development of crystals, which deposit in the joints causing pain, swelling and tenderness. This is known as a condition called gout.

**ADENURIC is used to prevent gout but is not used to treat acute attacks of gout (also called gout flares).**

## **2. What should I know before I take ADENURIC?**

### **Warnings**

**Do not take ADENURIC if:**

- you are allergic to febuxostat, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can take this medicine.

## **Check with your doctor if you have or have had:**

- taken any medication for any other condition
- heart disease, heart failure, a heart attack or a stroke
- kidney problems
- allergic reaction to allopurinol (a medicine used to treat gout)
- liver problems
- high uric acid levels as a result of cancer or Lesch-Nyhan syndrome
- thyroid problems
- lactose intolerance
- organ transplant.

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

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### **Acute gouty attacks (gout flares)**

Do not take ADENURIC if you are having an acute attack of gout and are not taking ADENURIC already. Your doctor will wait until the symptoms of the acute attack of gout have passed before starting you on ADENURIC.



If you have a gout flare while you are taking ADENURIC, do not stop taking this medicine.

## **Pregnancy and breastfeeding**

Check with your doctor if you are pregnant or intend to become pregnant. It is not known whether it may affect your developing baby if you take it during pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed. It is not known if the active ingredient in ADENURIC passes into breast milk and there is possibility that your baby may be affected.

Your doctor can discuss with you the risks and benefits involved.

## **Use in children**

Do not give ADENURIC to a child under the age of 18 years. The safety and efficacy in children younger than 18 years old has not been established.

### **3. What if I am taking other medicines?**

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

**Some medicines may interfere with ADENURIC and affect how it works. These include:**

- mercaptopurine, a medicine used to treat cancer

- azathioprine, a medicine used to treat certain immune system problems
- theophylline, a medicine to treat asthma and other respiratory disorders
- tacrolimus, a medicine used to suppress the immune system after an organ transplant
- phenytoin, a medicine used to treat epilepsy.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ADENURIC.**

## **4. How do I take ADENURIC?**

### **How much to take**

The usual dose is 40 mg or 80 mg once daily. A starting dose of 40 mg (half a tablet) is recommended and if your blood uric acid remains high after 2 to 4 weeks, the dose may be increased to 80 mg (1 whole tablet) once daily.

Your doctor will tell you how much to take. This depends on your condition and whether or not you are taking any other medicines. Follow the instructions provided and use ADENURIC until your doctor tells you to stop.

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

### **How to take ADENURIC**

40 mg Dose:

- You will need to break a tablet in half.
- To break the tablet, hold the tablet between your thumbs and index fingers close to the score line.
- Then, with the score line facing you, apply enough pressure to snap the tablet apart. Alternatively, use a tablet or pill cutter available from pharmacies.
- Swallow one half of the tablet with a full glass of water.
- Keep the other half of the tablet for your next dose.

80 mg Dose:

- Take one whole tablet with a full glass of water.

## **When to take ADENURIC**

Take your medicine at about the same time each day.

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

It does not matter if you take this medicine before or after food.

## **If you forget to take ADENURIC**

**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 you missed.**

This may increase the chance of you getting an unwanted side effect.

If you have trouble remember to take your medicine, ask your pharmacists for some hints.

## **If you take too much ADENURIC**

If you think that you have taken too much ADENURIC, you may need urgent medical attention.

### **You should immediately:**

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## **5. What should I know while taking ADENURIC?**

### **Things you should do**

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

- rash, including blisters and nodules

- 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.

These may be the first signs of a serious allergic reaction to ADENURIC. You may need urgent medical attention. Your doctor may decide to permanently stop treatment with ADENURIC.

**Keep all of your doctor's appointments so that your progress can be checked.**

Your doctor may do some blood tests from time to time to make sure the medicine is working and tolerated by you.

**Call your doctor straight away if you:**

- have an acute gout attack and you are already taking ADENURIC. Your doctor may prescribe other medicines to treat the symptoms of flares.

**Keep taking ADENURIC even if you have a flare. You may experience more flares and maybe worsening pain during the initial period of treatment. This is due to the way that ADENURIC and this class of medicines work. It is important that you continue to take ADENURIC and do not stop during a gout flare. Over time, gout flares will**

**occur less often and be less painful if you keep taking ADENURIC.**

- develop any of the following symptoms while you are taking ADENURIC. They may be signs of liver problems:
  - yellowing of skin and eyes (jaundice)
  - dark urine
  - fatigue
  - loss in appetite
  - pain in the right upper abdomen.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking ADENURIC.

Remind any doctor, dentist or pharmacist you visit that you are taking ADENURIC.

## **Things you should not do**

- Do not take ADENURIC to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.
- Do not stop taking this medicine or lower the dosage without checking with your doctor.

## **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how ADENURIC affects you.**

ADENURIC may cause drowsiness, dizziness, pins and needles, and blurred vision in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

## **Looking after your medicine**

Follow the instructions in the carton on how to take care of your medicine properly. Keep your tablets in the pack until it is time to take them.

Store it in a cool dry place below 30°C and away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

**Keep it where young children cannot reach it.**

## **Getting rid of any unwanted medicine**

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## **6. Are there any side effects?**

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

## Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"><li>● headache and dizziness</li><li>● nausea</li><li>● diarrhoea</li><li>● rash and itching</li><li>● reddening of the skin, psoriasis, eczema</li><li>● increase in gout symptoms such as red, swollen and painful joints (gout flares)</li><li>● localised swelling (oedema)</li><li>● joint or muscle pain or stiffness</li></ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

## Serious side effects

Serious side effects	What to do
<b>Heart-related:</b> <ul style="list-style-type: none"><li>● chest pain or discomfort</li><li>● shortness of breath or trouble breathing</li><li>● dizziness, fainting, feeling lightheaded</li></ul>	<b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b>



<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● rapid or irregular heartbeat</li> <li>● numbness or weakness on one side of your body</li> <li>● slurring of speech</li> <li>● sudden blurry vision</li> <li>● sudden severe headache</li> </ul> <p><b>Allergic reaction-related:</b></p> <ul style="list-style-type: none"> <li>● sudden rash, itching or hives on the skin</li> <li>● swelling of the face, lips, tongue or other parts of the body</li> <li>● shortness of breath, wheezing or trouble breathing</li> </ul> <p><b>Severe skin reaction-related:</b></p> <ul style="list-style-type: none"> <li>● painful red areas, large blisters and peeling of layers of skin</li> </ul> <p><b>Liver-related:</b></p> <ul style="list-style-type: none"> <li>● yellowing of skin and eyes (jaundice)</li> <li>● dark urine</li> <li>● fatigue</li> </ul>	

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● loss in appetite</li> <li>● pain in the right upper abdomen</li> </ul> <p><b>Pancreatic inflammation-related:</b></p> <ul style="list-style-type: none"> <li>● abdominal pain</li> <li>● nausea</li> <li>● vomiting</li> </ul> <p><b>General body-related:</b></p> <ul style="list-style-type: none"> <li>● pinkish, itchy swellings on the skin</li> <li>● fever or feeling hot</li> <li>● signs of lung infection (pneumonia) such as rapid or difficulty breathing, chest pain worsening when breathing, cough, fever chills or fatigue</li> <li>● urinary tract infection</li> <li>● thyroid problems</li> <li>● erectile problems</li> <li>● severe abdominal pain</li> <li>● pain in extremity</li> <li>● severe muscle pain</li> <li>● fatigue</li> </ul>	

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● blood in urine, abnormal frequent urination, urge to urinate or burning sensation when urinating</li> <li>● ringing in the ears</li> </ul>	

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## **Reporting side effects**

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## **7. Product details**

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

## What ADENURIC contains

<b>Active ingredient (main ingredient)</b>	febuxostat
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>• lactose monohydrate</li><li>• microcrystalline cellulose</li><li>• magnesium stearate</li><li>• hypromellose</li><li>• croscarmellose sodium</li><li>• silicon dioxide.</li></ul> <p>Core tablets are coated with Opadry II Yellow 85F42129 containing:</p> <ul style="list-style-type: none"><li>• polyvinyl alcohol</li><li>• titanium dioxide</li><li>• macrogol 3350</li><li>• purified talc</li><li>• iron oxide yellow.</li></ul>
<b>Potential allergens</b>	lactose monohydrate

**Do not take this medicine if you are allergic to any of these ingredients. ADENURIC does not contain sucrose, gluten, tartrazine or any other azo dyes.**

## **What ADENURIC looks like**

ADENURIC tablets are available in one strength of 80 mg (AUST R 205556). The tablets are pale-yellow to yellow in colour and rectangular in shape. The tablets are scored on one side and marked "80" on the other side.

ADENURIC tablets are available in blister packs of 4, 8 or 28 tablets. Not all pack sizes may be available.

## **Who distributes ADENURIC**

A. Menarini Australia Pty Ltd

Level 8, 67 Albert Ave, Chatswood NSW 2067

Medical Information: 1800 644 542

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This leaflet was prepared in November 2022

For the most up to date version of this leaflet, please go to [www.menarini.com.au/cmi](http://www.menarini.com.au/cmi)

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