

APO-Allopurinol

contains the active ingredient, allopurinol (al-oe-PUR-in-ol)

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine.

Ask your doctor or pharmacist if you do not understand anything or are worried about taking your medicine.

This leaflet answers some common questions about allopurinol.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. Some more recent information on your

medicine may be available. Speak to your pharmacist or doctor to obtain the most up-to-date information.

All medicines have risks and benefits. Your doctor or pharmacist has weighed the risks of you taking this medicine against the benefits they expect it will have for you.

Keep this leaflet with your medicine.

You may need to read it again.

What allopurinol is used for

The name of your medicine is APO-Allopurinol. It contains the active ingredient, allopurinol.

Allopurinol is used to treat:

- gouty arthritis or gout
- kidney stones
- rare conditions where high levels of uric acid occur in the blood (for example, Lesch-Nyhan syndrome).

Allopurinol is used to treat the symptoms of these conditions, but it will not cure them. Also, it will not help treat the pain that occurs in an acute attack of gout.

How it works

Allopurinol belongs to a group of medicines called anti-uricaemic agents. These medicines work by reducing high levels of uric acid in the body, which are usually due to gout.

Excess amounts of uric acid in the blood may lead to uric acid crystals being made and deposited in the joints, thereby causing pain, swelling and tenderness.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed allopurinol for another reason.

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

There is no evidence that this medicine is addictive.

Use in children

There is very little information to recommend the use of this medicine in children. Allopurinol should only be taken by children if a doctor has prescribed it.

Before you take allopurinol

When you must not take it

Do not take this medicine if you have had an allergic reaction to allopurinol or any of the ingredients listed at the end of this leaflet. Symptoms of an allergic reaction may include: shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; muscle pain or tenderness or joint pain; or rash, itching or hives on the skin.

Do not take allopurinol if you or a member of your immediate family has been diagnosed with

haemochromatosis (a disease involving too much iron in the body) and you are taking iron salts.

Do not take this medicine after the expiry date (EXP) printed on the pack.

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

Do not take this medicine if the packaging is torn, shows signs of tampering or if the tablets do not seem quite right

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you:

1. have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. have or have had any medical conditions, especially the following:
 - kidney problems, including kidney stones
 - liver problems

- high blood pressure
 - heart problems
 - conditions where the levels of uric acid are abnormally high
 - cancer or tumours.
3. are having an attack of gout.

Treatment with allopurinol should not be started until the attack has stopped, otherwise more attacks may occur.

(However, if an attack of gout occurs when a person is already taking allopurinol, it can be continued).

4. are pregnant or intend to become pregnant.

Your doctor will discuss with you the risks and benefits of taking allopurinol during pregnancy.

5. are breast-feeding or plan to breast-feed.

Allopurinol passes into breast milk and may affect your baby. Your doctor will discuss with you the risks and benefits of taking allopurinol when breast-feeding.

If you have not told your doctor about any of the above, tell them before you start taking this medicine.

Taking other medicines

Tell your doctor or pharmacist 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 allopurinol may interfere with each other. These include:

- some medicines used to treat high blood pressure or heart problems
- thiazide diuretics (a certain type of water tablet)
- mercaptopurine, azathioprine or cyclosporin - medicines used to suppress the immune system
- aspirin and other medicines known as salicylates
- probenecid, a medicine used to treat gout
- warfarin, used to help prevent blood clots
- chlorpropamide, a medicine used to treat diabetes
- phenytoin, a medicine used to treat epilepsy
- certain antibiotics such as ampicillin and amoxycillin
- theophylline, a medicine used to treat asthma
- vidarabine, an anti-viral medicine.

These medicines may be affected by allopurinol 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 and pharmacist can tell you if you are taking any of these medicines. They may also have more information on medicines to be careful with or avoid while taking allopurinol.

Other interactions not listed above may also occur.

How to take this medicine

Follow all directions given to you by your doctor or pharmacist carefully.

They may be different to the information in this leaflet.

If you do not understand any written instructions, ask your doctor or pharmacist for help.

How much to take

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

- The usual adult dose range is:100 - 200 mg per day for mild conditions
- 300 - 600mg per day for moderately severe conditions
- 700 - 900mg per day for severe conditions.

People over 65 years of age, and those with kidney and/or liver problems should be started on the lowest dose possible to control uric acid production.

Children under 15 years of age usually take 100 - 400 mg per day.

How to take it

Swallow the tablets with a glass of water.

When to take it

Take your medicine immediately after food, as this will lessen the chance of a stomach upset.

Take your medicine at the same time each day.

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

Allopurinol is usually taken once daily. However, if your dose is more than 300 mg, your doctor may advise you to take your medicine twice a day. Then, it should be taken morning and night, after breakfast and dinner.

How long to take it for

Continue taking your medicine for as long as your doctor tells you.

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

If you forget to take it

If you miss a dose, and it is more than 4 hours until your next dose is due, take the missed dose as soon as you remember.

If it is less than 4 hours to your next dose, do not take the dose you missed and take your next dose when you

are meant to.

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

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.

If you take too much (overdose)

Immediately telephone your doctor or pharmacist or the Poisons Information Centre (telephone 13

11 26), or go to Accident and Emergency Department at your nearest hospital, if you think that you or anyone else may have taken too many allopurinol.

Do this even if there are no signs of discomfort or poisoning.
You may need urgent medical attention.

If you take too much allopurinol, you may feel some or all of the

following:

- nausea
- vomiting
- diarrhoea
- dizziness.

While you are taking allopurinol

Things you must do

You must immediately stop taking allopurinol if a skin rash or signs of an allergic reaction occur - immediately tell your doctor.

The signs of an allergic reaction were listed earlier in this leaflet.

You should drink at least two litres

(8 - 10 glasses) of fluid each day.

This will assist in reducing the uric acid levels in your body and prevent kidney stones from forming.

Tell your doctor if you have an acute attack of gout while you are taking allopurinol.

Your doctor may prescribe a medicine to relieve the acute attack.

You can continue taking allopurinol.

Tell any other doctors, dentists or pharmacists who are treating you that you are taking allopurinol.

Tell your doctor immediately if you become pregnant while you are taking this medicine.

If you are about to have any surgery, tell the surgeon, dentist or doctor that you are taking this medicine.

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

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

Go to your doctor regularly for a check-up.

Your doctor may occasionally do tests to make sure this medicine is working and to prevent side effects.

Things you must not do

Do not take this medicine to treat an acute attack of gout.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Do not take this medicine to treat any other complaints unless your doctor tells you to.

Do not stop taking your medicine, or change the dosage, without checking with your doctor

Things to be careful of

Make sure you know how allopurinol affects you before you drive a car, operate machinery or do anything else that could be dangerous if you are drowsy.

As with other medicines, allopurinol may cause drowsiness, dizziness or lack of co-ordination in some people

Side effects of allopurinol

All medicines may have some unwanted side effects. Sometimes they are serious, but most of the time they are not.

If you are over 65 years of age, have kidney and/or liver problems, you may have an increased chance of getting side effects.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking allopurinol.

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

Following is a list of possible side effects. Do not be alarmed by this list. You may not experience any of them.

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

- stomach upsets, including nausea, vomiting or diarrhoea
- dizziness, drowsiness or unsteadiness when walking
- change in bowel habits
- headache
- change in taste sensation
- sleeplessness
- hair loss or change in hair colour.

These are the more common side effects of allopurinol.
Mostly these are mild and short-lived.

Tell your doctor as soon as possible if you notice any of the following:

- changes in vision
- tingling or numbness of the hands or feet
- fever, chills, sore throat or mouth ulcers
- a change in the amount of urine passed, going to the toilet more often or a burning feeling while passing urine
- blood in your urine

- yellowing of the skin and eyes
- (jaundice)
- generally feeling of being unwell or depressed
- frequent infections such as fever, severe chills, sore throat or mouth ulcers
- bleeding or bruising more easily
- angina or palpitations
- swelling of the hands, ankles or legs.

These may be serious side effects. You may need medical attention. Most of these side effects are rare.

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

- asthma, wheezing or shortness of breath
- swelling of the face, lips, tongue or throat which may cause difficulty in breathing
- sudden or severe itching, skin
- rash or hives, other skin problems
- fainting, seizures or fits
- pain or tightness in the chest.

These are very 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 or pharmacist if you notice anything that is making you feel unwell.

After taking this medicine

Storage

Keep your medicine in its original packaging until it is time to take them. If you take the tablets out of their original packaging they may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25°C.

Do not store your medicine, or any other medicine, in the bathroom or near a sink.

Do not leave it on a window sill or in the car.

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 this medicine or it has passed its expiry date, ask your pharmacist what to do with any medicine that is left over. Where to go for further information

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition.

Product description

What APO-Allopurinol looks like

100 mg tablets:

White to off-white, round, biconvex tablets coded with "U4A" and scored on the upper face and bottom face plain..

They are packed in a bottle of 200 tablets.

300 mg tablets:

White, round, biconvex tablets coded with "C9B" and scored on the upper face and bottom face plain. They are packed in a blister pack of 60 tablets.* Not all strengths, pack types and/or pack sizes may be available.

Ingredients

Each tablet contains 100 mg or 300 mg of allopurinol as the active ingredient.

- It also contains the following inactive ingredients:
- povidone
- maize starch
- lactose monohydrate
- magnesium stearate

This medicine contains lactose but is gluten-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

APO-ALLOPURINOL 100 mg AUST R 218874

APO-ALLOPURINOL 300 mg AUST R 218875

Sponsor

Arrow Pharma Pty Ltd

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