

Allopurinol APOTEX Tablets

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

Consumer Medicine Information

What is in this leaflet

Read this leaflet carefully before 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. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from www.apotex.com.au.

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.

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 this medicine is used for

Allopurinol APOTEX Tablets 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).

It belongs to a group of medicines called anti-uricaemic agents.

This medicine works by reducing the production of uric acid in the body. High levels of uric acid may cause gout attacks or kidney stones. Allopurinol is used to prevent gout attacks, not to treat them once they occur.

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

Your doctor may have prescribed it for another reason.

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

Use in children

There is not enough information to recommend the use of this medicine for children.

Before you take this medicine

When you must not take it

Do not take this medicine if you have an allergy to:

- any medicine containing allopurinol
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing

- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin
- muscle pain or tenderness or joint pain

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

Do not take this medicine if you have or have had any of the following:

- 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 printed on the pack or if the packaging is torn or shows signs of tampering.

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 have allergies to any other medicines, foods, preservatives or dyes.

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

- 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.

Tell your doctor if you are currently 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).

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

Allopurinol passes into breast milk and may affect your baby. Your doctor can discuss with you the risks and benefits involved.

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 get without a prescription from your pharmacy, supermarket or health food shop

Some medicines and allopurinol may interact 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 amoxicillin
- theophylline, a medicine used to treat asthma
- adenine arabinoside ('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 medicines, or you may need to take different medicines.

Other medicines not listed above may also interact with allopurinol.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take this medicine

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

They may differ from the information contained in this leaflet.

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

How much to take

Your doctor will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

The usual adult dose range is:

- 100 - 200 mg per day for mild conditions
- 300 - 600 mg per day for moderately severe conditions
- 700 - 900 mg 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 whole with a full 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.

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.

Make sure you have enough to last over weekends and holidays.

If you forget to take it

If it is less than 4 hours to your next dose, skip the missed dose and take your next dose at the usual time.

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.

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)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital.

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

You may need urgent medical attention.

Symptoms of an overdose may include:

- nausea
- vomiting
- diarrhoea
- dizziness.

While you are taking this medicine

Things you must do

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.

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

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

If you become pregnant or plan to breastfeed while taking this medicine, tell your doctor immediately.

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

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

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you must not do

Do not take this medicine 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 your medicine or lower the dosage without checking with your doctor.

If you stop taking it suddenly, your condition may worsen. If possible, your doctor will gradually reduce the amount you take each day before stopping the medicine completely.

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

Things to be careful of

Be careful driving or operating machinery until you know how this medicine affects you.

This medicine may cause (dizziness, drowsiness, lack of co-ordination etc.) in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Possible side effects

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

Allopurinol helps most people but it may have unwanted side effects in a few people. All medicines can have side effects.

Sometimes they are serious but most of the time they are not. You may need medical attention if you get some of the side effects. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

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:

- 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

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
- 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.

The above list includes serious side effects that may require medical attention.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at 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.

The above list includes 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.

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

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take the tablets out of their original packaging it 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 tells you to stop taking this medicine or it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What Allopurinol APOTEX Tablets looks like

Allopurinol 100 mg tablets:

White, to off-white, colored round, biconvex uncoated tablets with 'AL' & '100' separated

by breakline on one side and plain on the other side.

Bottle (HDPE white opaque bottle with screw cap) of 200's tablets.

Blister Pack (Clear PVDC/PVC/ Aluminium silver foil) of 60's tablets.

Allopurinol 300 mg tablets:

Peach colored, round, biconvex uncoated tablets coded with 'AL' & '300' separated by breakline on one side and plain on other side.

Blister Pack (Clear PVDC/PVC/ Aluminium silver foil) of 60's tablets.

* Not all strengths, pack types and/or pack sizes may be available.

Ingredients

Each allopurinol tablet contains allopurinol as the active ingredient. In addition, each tablet contains the following inactive ingredients: It also contains the following inactive ingredients:

- lactose monohydrate
- maize starch
- povidone
- sodium starch glycolate type A
- sunset yellow FCF
- stearic acid

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

Australian Registration Numbers

Allopurinol APOTEX 100mg bottle: AUST R 269652

Allopurinol APOTEX 300mg blister: AUST R 269638

Sponsor

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