

ALLOPURINOL ALPHAPHARM

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.

1. Why am I taking ALLOPURINOL ALPHAPHARM?

ALLOPURINOL ALPHAPHARM contains the active ingredient allopurinol. ALLOPURINOL ALPHAPHARM is used to treat: gouty arthritis or gout, kidney stones and rare conditions like Lesch-Nyhan syndrome.

For more information, see Section [1. Why am I taking ALLOPURINOL ALPHAPHARM?](#) in the full CMI.

2. What should I know before I take ALLOPURINOL ALPHAPHARM?

Do not take if you have ever had an allergic reaction to ALLOPURINOL ALPHAPHARM 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, or are pregnant or plan to become pregnant or are breastfeeding.**

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

3. What if I am taking other medicines?

Some medicines may interfere with ALLOPURINOL ALPHAPHARM 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 ALLOPURINOL ALPHAPHARM?

Swallow the tablets whole with a full glass of water. More instructions can be found in Section [4. How do I take ALLOPURINOL ALPHAPHARM?](#) in the full CMI.

5. What should I know while taking ALLOPURINOL ALPHAPHARM?

Things you should do	<ul style="list-style-type: none">● Drink at least two litres (8-10 glasses) of fluid each day.● Stop taking this medicine immediately if you develop a skin rash or signs of an allergic reaction.
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	<ul style="list-style-type: none"> ● Tell your doctor if you have an acute attack of gout while you are taking this medicine. ● Tell your doctor immediately if you become pregnant or plan to breastfeed while taking this medicine.
<p>Things you should not do</p>	<ul style="list-style-type: none"> ● Do not take this medicine to treat any other complaints unless your doctor tells you to. ● Do not stop taking this medicine or lower the dosage without checking with your doctor. ● Do not give this medicine to anyone else, even if they have the same condition as you. ● Do not take this medicine to treat an acute attack of gout.
<p>Driving or using machines</p>	<ul style="list-style-type: none"> ● ALLOPURINOL ALPHAPHARM may cause dizziness, drowsiness, lack of co-ordination in some people. Make sure

	you know how you are affected by this medicine before you drive or use machinery.
Drinking alcohol	<ul style="list-style-type: none"> • Tell your doctor if you drink alcohol.
Looking after your medicine	<ul style="list-style-type: none"> • Keep ALLOPURINOL ALPHAPHARM in a cool dry place where the temperature stays below 25°C.

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

6. Are there any side effects?

Stomach upsets, including nausea, vomiting, dizziness, drowsiness, headache, change in taste sensation, sleeplessness, hair loss. **Serious side effects:** changes in vision, tingling or numbness of the hands or feet, a change in the amount of urine passed, 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. **Very serious side effects:** 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 flaking, skin rash or hives, other skin problems, fainting, seizures or

fits, pain or tightness in the chest. 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.

ALLOPURINOL ALPHAPHARM

Active ingredient(s): *allopurinol*

Consumer Medicine Information (CMI)

This leaflet provides important information about taking ALLOPURINOL ALPHAPHARM. **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 ALLOPURINOL ALPHAPHARM.**

Where to find information in this leaflet:

1. Why am I taking ALLOPURINOL ALPHAPHARM?
- [2. What should I know before I take ALLOPURINOL ALPHAPHARM?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take ALLOPURINOL ALPHAPHARM?](#)
- [5. What should I know while taking ALLOPURINOL ALPHAPHARM?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I taking ALLOPURINOL ALPHAPHARM?

ALLOPURINOL ALPHAPHARM contains the active ingredient allopurinol.

ALLOPURINOL ALPHAPHARM is used to treat:

- gouty arthritis or gout, a condition of painful swollen joints caused by uric acid crystals
- 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.

ALLOPURINOL ALPHAPHARM works by reducing the production of uric acid in the body, therefore helping to prevent the formation of deposits of uric acid crystals. Deposits of uric acid crystals in the body can cause a variety of medical problems.

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. It will not help treat the pain that occurs in an acute attack of gout.

Ask your doctor if you have any questions about why ALLOPURINOL ALPHAPHARM has been prescribed for you.

Your doctor may have prescribed it for another reason.

There is no evidence that ALLOPURINOL ALPHAPHARM is addictive.

2. What should I know before I take ALLOPURINOL ALPHAPHARM?

Warnings

Do not take ALLOPURINOL ALPHAPHARM if:

- you are allergic to allopurinol, or any of the ingredients listed at the end of this leaflet.
Some of the symptoms of an allergic reaction may include:
 - skin rash, itching or hives
 - swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing or other parts of the body
 - wheezing or difficulty breathing
 - shortness of breath
 - 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 emergency department at the nearest hospital.

Always check the ingredients to make sure you can take this medicine.

- 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.

- you are having an acute attack of gout unless advised by your doctor.
- the expiry date has passed or the packaging shows signs of tampering, or the tablets do not look like the tablets described at the end of this leaflet.

Check with your doctor if you:

- have, or have had any other medical conditions including:
 - kidney problems, including kidney stones
 - liver problems
 - high blood pressure
 - heart failure or other heart problems
 - conditions where the levels of uric acid are abnormally high
 - cancer or tumours
 - thyroid problems
 - diabetes
 - epilepsy
 - haemochromatosis

Your doctor may want to take special care if you have any of these conditions.

- are allergic to any other medicines, foods, dyes or preservatives.

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

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).

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?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Your doctor will discuss the risks and benefits of taking ALLOPURINOL ALPHAPHARM during pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

ALLOPURINOL ALPHAPHARM passes into breast milk and may affect your baby. Your doctor will discuss with you the risks and benefits of taking ALLOPURINOL ALPHAPHARM when breastfeeding.

Use in children

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

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 ALLOPURINOL ALPHAPHARM and affect how it works. These include:

- some medicines used to treat high blood pressure or heart problems
- thiazide diuretics or fluid tablets
- azathioprine and ciclosporin, medicines used to prevent organ transplant rejection or to treat certain immune system problems
- mercaptopurine monohydrate, a medicine used in the treatment of leukaemia
- aspirin and other medicines known as salicylates
- probenecid, a medicine used to treat gout or hyperuricaemia (high levels of uric acid in the blood)
- warfarin and other coumarin type anticoagulant medicines, 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
- aluminium hydroxide, a medicine used to treat the symptoms of too much stomach acid

- adenine arabinoside ('Vidarabine'), an anti-viral medicine
- medicines used for cancer (e.g. cyclophosphamide, doxorubicin)
- didanosine, used to treat HIV infection.

Other medicines not listed above may also interact with allopurinol.

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

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

4. How do I take ALLOPURINOL ALPHAPHARM?

How much to take

- The dose varies from person to person. Your doctor will tell you how much to take. Your doctor may advise you to take a different dose. This will depend on your condition and whether you are taking any other medicines.
- Follow the instructions provided and take ALLOPURINOL ALPHAPHARM until your doctor tells you to stop.
- 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 ALLOPURINOL ALPHAPHARM

- Swallow the tablets whole with a full glass of water.

When to take ALLOPURINOL ALPHAPHARM

- ALLOPURINOL ALPHAPHARM should be taken 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 ALPHAPHARM 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 to long to take ALLOPURINOL ALPHAPHARM

- **Continue taking ALLOPURINOL ALPHAPHARM for as long as your doctor tells you.**

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

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

If you forget to take ALLOPURINOL ALPHAPHARM

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 tablets 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 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 have taken too much ALLOPURINOL ALPHAPHARM

If you think that you or anyone else has taken too much ALLOPURINOL ALPHAPHARM urgent medical attention may be needed.

You should immediately:

- phone the Poisons Information Centre **(by calling 13 11 26)** for advice, 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.

You may need urgent medical attention.

Symptoms of an overdose may include:

- nausea
- vomiting
- diarrhoea
- dizziness.

5. What should I know while taking ALLOPURINOL ALPHAPHARM?

Things you should 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.

- **Stop taking ALLOPURINOL ALPHAPHARM immediately if you develop a skin rash or any other sign of an allergic reaction.**
- **Tell your doctor if you have an acute attack of gout while you are taking ALLOPURINOL ALPHAPHARM.**

Your doctor may prescribe a medicine to relieve the acute attack. You can continue taking allopurinol.

- **If you are about to start any new medicine, remind your doctor and pharmacist that you are taking ALLOPURINOL ALPHAPHARM.**
- **Remind any doctor, dentist or pharmacist you visit that you are taking ALLOPURINOL ALPHAPHARM.**
- **If you are going to have surgery, tell the surgeon or anaesthetist that you are taking ALLOPURINOL ALPHAPHARM.**
- **If you become pregnant or plan to breastfeed while taking ALLOPURINOL ALPHAPHARM, tell your doctor immediately.**

- **If you are about to have any blood tests, tell your doctor that you are taking ALLOPURINOL ALPHAPHARM.**
- **Keep all of your doctor's appointments so that your progress can be checked.**

You may need to have blood or urine tests from time to time to make sure ALLOPURINOL ALPHAPHARM is working and to prevent unwanted side effects.

- **Tell your doctor if you feel ALLOPURINOL ALPHAPHARM is not helping your condition.**

If you continue to have painful attacks of gout, your doctor may need to adjust your treatment.

- **Tell your doctor if, for any reason, you have not taken ALLOPURINOL ALPHAPHARM exactly as prescribed.**

Otherwise, your doctor may adjust your treatment unnecessarily.

Things you should not do

- Do not take ALLOPURINOL ALPHAPHARM to treat any other conditions unless your doctor tells you to.
- Do not give ALLOPURINOL ALPHAPHARM to anyone else, even if they have the same condition as you.
- Do not stop taking ALLOPURINOL ALPHAPHARM 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 ALLOPURINOL ALPHAPHARM to treat an acute attack of gout.

Your doctor will prescribe another medicine such as colchicine or a non-steroidal anti-inflammatory drug (NSAID) to relieve an acute attack of gout.

Things to be careful of

- **Certain foods are best avoided when you have gout.**

Food such as organ meats, anchovies and yeast extracts (includes Vegemite®) can increase the levels of uric acid in your body. Ask your doctor or pharmacist for more advice about which foods to avoid.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how ALLOPURINOL ALPHAPHARM affects you.

ALLOPURINOL ALPHAPHARM may cause dizziness, drowsiness, lack of co-ordination in some people. If any of these occur, do not drive, operate machinery or do anything else that could be dangerous.

Drinking alcohol

Avoid drinking alcohol while taking ALLOPURINOL ALPHAPHARM.

Combining ALLOPURINOL ALPHAPHARM and alcohol can make you more sleepy, dizzy or lightheaded. Alcohol may also increase the formation of uric acid.

Tell your doctor if you drink alcohol.

Looking after your medicine

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

If you take tablets out of the bottle they may not keep well.

- Keep your tablets in a cool dry place where the temperature stays below 25°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place 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.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

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

Getting rid of any unwanted medicine

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

Do not take 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.

People with liver and kidney problems have an increased chance of experiencing side effects.

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

You may not experience any of them.

The most common side effect is skin rash. Stop treatment with ALLOPURINOL ALPHAPHARM immediately and contact your doctor if a rash does occur.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">● stomach upsets, including nausea, vomiting or diarrhoea● dizziness, drowsiness or unsteadiness when walking	Speak to your doctor if you have any of these less serious side effects and they worry you.

Less serious side effects	What to do
<ul style="list-style-type: none"> ● change in bowel habits ● headache ● change in taste sensation ● sleeplessness ● hair loss or change in hair colour. 	

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> ● 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, 	<p>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.</p>

Serious side effects	What to do
<p>sore throat or mouth ulcers</p> <ul style="list-style-type: none"> ● bleeding or bruising more easily ● angina or palpitations ● swelling of the hands, ankles or legs. 	

Very serious side effects

Very serious side effects	What to do
<ul style="list-style-type: none"> ● asthma, wheezing or shortness of breath ● swelling of the face, lips, tongue or throat which may cause difficulty in swallowing or breathing ● sudden or severe itching, skin flaking, skin rash or hives, other skin problems ● fainting, seizures or fits ● pain or tightness in the chest. ● ● 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects.</p> <p>These side effects are rare.</p>

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.

Some of these side effects (e.g. high blood pressure) can only be found when your doctor does tests from time to time to check your progress.

Check with your doctor as soon as possible if you have any problems while taking ALLOPURINOL ALPHAPHARM, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

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. 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 ALLOPURINOL ALPHAPHARM 100 contains

Active ingredient (main ingredient)	allopurinol (100 mg)
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• lactose monohydrate• maize starch• povidone• macrogol 8000• sodium lauryl sulfate• purified talc• magnesium stearate
Potential allergens	<ul style="list-style-type: none">• galactose• sulfites• sugars as lactose

ALLOPURINOL ALPHAPHARM 100 is available in bottles of 200 tablets.

What ALLOPURINOL ALPHAPHARM 300 contains

Active ingredient (main ingredient)	allopurinol (300 mg)
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• maize starch• povidone

	<ul style="list-style-type: none"> • maltodextrin • sodium starch glycollate • microcrystalline cellulose • magnesium stearate
Potential allergens	<ul style="list-style-type: none"> • sulfites

ALLOPURINOL ALPHAPHARM 300 is available in bottles of 60 tablets.

Do not take this medicine if you are allergic to any of these ingredients.

What ALLOPURINOL ALPHAPHARM looks like

- **ALLOPURINOL ALPHAPHARM 100** - 9.5 mm white normal convex tablet marked "AL/100" on one side and "G" on the reverse (AUST R 27969).
- **ALLOPURINOL ALPHAPHARM 300** - 11 mm white normal convex tablet marked "AL/300" on one side and "G" on the reverse (AUST R 17708).

Who distributes ALLOPURINOL ALPHAPHARM

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

This leaflet was prepared in May 2025.

ALLOPURINOL ALPHAPHARM_cmi\May25/01