

Front

Package leaflet: Information for the user
Allopurinol Tablets BP 100mg
(allopurinol)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Allopurinol Tablets are and what they are used for
2. What you need to know before you take Allopurinol Tablets
3. How to take Allopurinol Tablets
4. Possible side effects
5. How to store Allopurinol Tablets
6. Contents of the pack and other information.

1. What Allopurinol Tablets are and what they are used for

Allopurinol Tablets contains the active substance allopurinol. It belongs to a group of medicines called enzyme inhibitors. It works by slowing down the speed of certain chemical reactions in your body to lower the level of uric acid in the blood and urine.

Allopurinol Tablets are used:

- to reduce or prevent the formation of urate/uric acid deposition in conditions where your body produces too much of a substance called uric acid. These may include gout or some types of kidney stones or certain other types of kidney problems or when you are having treatment for cancer or some other conditions. In gout the uric acid builds up in your joints and tendons as crystals. These crystals cause an inflammatory reaction. The inflammation causes the skin around certain joints to become swollen, tender and sore when only slightly touched. You can also find you get severe pain when the joint is moved.
- to treat certain enzyme disorders, in particular Lesch-Nyhan syndrome.

2. What you need to know before you take Allopurinol Tablets

Do not take Allopurinol Tablets:

- if you are allergic (hypersensitive) to Allopurinol or any of the other ingredients of this medicine (listed in section 6)
- If you are not sure, talk to your doctor or pharmacist before taking Allopurinol Tablets.

Warnings and Precautions

Talk to your doctor or pharmacist before taking Allopurinol Tablets:

- if you are of Han Chinese, African or Indian origin
- if you have problems with your liver or kidneys. Your doctor may give you a lower dose or ask you to take it less often than each day. They will also monitor you more closely.
- if you have heart problems or high blood pressure and you take diuretics and/or a medicine called ACE-inhibitors.
- if you are currently having an attack of gout.
- if you have thyroid problems

Take special care with Allopurinol Tablets:

- serious skin rashes (Hypersensitivity syndrome, Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported in patients taking allopurinol. Frequently, the rash can involve ulcers of the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes). These serious skin rashes are often preceded by influenza-like symptoms fever, headache, body ache (flu-like symptoms). The rash may progress to widespread blistering and peeling of the skin. These serious skin reactions can be more common in people of Han Chinese, Thai or Korean origin. Chronic kidney disease may increase the risk in these patients additionally. If you develop a rash or these skin symptoms, **stop taking allopurinol and contact your doctor immediately.**
- if you have cancer or Lesch-Nyhan syndrome the amount of uric acid may increase in your urine. To prevent this, you need to assure you drink sufficiently to dilute your urine.
- if in case you have kidney stones, the kidney stones will become smaller and may enter your urinary tract.

Children

Use in children is rarely indicated, except in some types of cancer (especially leukaemia) and certain enzyme disorders such as Lesch-Nyhan syndrome.

Other medicines and Allopurinol Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

This includes medicines obtained without a prescription, including herbal medicines. This is because Allopurinol Tablets can affect the way some medicines work. Also some other medicines can affect the way Allopurinol tablets work. For example -

- 6-mercaptopurine used to treat cancer of the blood cells
- medicines used to reduce your immune response (immunosuppressant) e.g. azathiopine, ciclosporin
- vidarabine, used to treat herpes or chickenpox
- antibiotics e.g. amoxicillin or ampicillin
- aspirin
- theophylline, used for breathing problems
- medicines used for fits (epilepsy) e.g. phenytoin
- didanosine, used to treat HIV infection
- medicines used to treat diabetes e.g. chlorpropamide
- medicines used to thin your blood (anticoagulants) such as warfarin
- medicines for heart problems or high blood pressure such as 'ACE inhibitors' or water tablets (diuretics)
- any other medicine to treat gout e.g. probenecid

If aluminium hydroxide is taken at the same time, this may weaken the effect of allopurinol. There should be an interval of at least 3 hours between taking both medicines.

When allopurinol is taken at the same time as some chemotherapy medicines (e.g. cyclophosphamide, doxorubicin, bleomycin, procarbazine, alkyl halogenides), blood disorders occur more frequently.

Blood count monitoring should therefore be performed at regular intervals.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Allopurinol is excreted in the human breast milk. Allopurinol during breastfeeding is not recommended.

Driving and using machines

Allopurinol Tablets may cause drowsiness, affect your co-ordination, affect your vision or make you feel dizzy. If you experience these symptoms you should avoid driving or operating machinery.

Allopurinol Tablet contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Information on sodium content

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Allopurinol Tablets

Always take Allopurinol tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

For **oral use** only. Allopurinol Tablets should be taken after food and swallow it with a glass of water.

You doctor will usually start with a low dose of allopurinol (e.g. 100 mg/day), to reduce the risk of possible side effects. Your dose will be increased if necessary.

Adults: (Over 18 years)

The recommended dose ranges from 100 to 900 mg each day. Initially 100 to 300mg per day is taken as a single dose which will be increased if necessary.

Use in children: (under 15 years)

The recommended dose is 10 to 20 milligrams per kilogram body weight/day up to a maximum of 400mg daily.

Use in the elderly: (over 65 years)

The lowest dosage possible will be given as recommended by your doctor.

Use in patients with kidney damage:

The level and frequency of dosage should be recommended by your doctor. The dose may need to be decreased depending on blood uric acid levels due to kidney damage which mean it takes longer to excrete Allopurinol.

Use in patients on kidney dialysis:

Allopurinol and its by-products are removed by dialysis. If dialysis is done frequently 300 to 400mg of Allopurinol may be given after each dialysis with none in the interim.

The dose should be adjusted by checking blood uric acid and/or urinary uric acid levels at

200 mm

400 mm

8.1 mm

17 mm

8.1 mm

200 mm

33.33 mm

166.65 mm

8.6 mm

17 mm

8.6 mm

150 mm

Back

appropriate intervals which will be done by your doctor. It might take one to three weeks for blood and/or urinary uric acid to return to the desired levels.

If you take more Allopurinol Tablets than you should

If you or someone else swallow several of these tablets together, contact your doctor or nearest hospital emergency department immediately. Always take the box, this leaflet and any tablets that are left over with you, if you can. Signs of an overdose may include nausea, vomiting, diarrhoea and dizziness.

If you forget to take Allopurinol Tablets

If you miss a dose, take it as soon as you remember and carry on as before. If it is almost time for your next dose, skip the forgotten dose and continue as usual. Do not take a double dose to make up for a forgotten dose.

If you stop taking Allopurinol Tablets

Do not stop taking Allopurinol 100mg tablets without first discussing it with your doctor.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Allopurinol Tablets can cause side effects, although not everyone gets them.

Serious side effects

If you experience any of the following, stop your tablets and tell your doctor immediately:

Allergic reaction

If you notice any of these signs, stop taking Allopurinol tablets and seek medical attention immediately.

Uncommon (may affect less than 1 in 100 people)

If you have a hypersensitivity (allergic) reaction, stop taking Allopurinol Tablets and see a doctor straight away.

The signs may include:

- flaking skin, boils or sore lips and mouth
- very rarely signs may include sudden wheeziness, fluttering or tightness in the chest and collapse.

Rare (may affect less than 1 in 1000 people)

- fever and chills, headache, aching muscles (flu-like symptoms) and generally feeling unwell
- serious hypersensitivity reactions involving fever, skin rash, joint pain, and abnormalities in blood and liver function tests (these may be signs of a multi-organ sensitivity disorder).
- bleeding in the lips, eyes, mouth, nose or genitals.
- any changes to your skin, for example; ulcers of the mouth, throat, nose, genitals, conjunctivitis (red and swollen eyes), widespread blisters or peeling.

Very rare (may affect up to 1 in 10,000 people)

- serious allergic reaction which causes swelling of the face or throat
- serious potentially life-threatening allergic reaction

Do not take any more tablets unless your doctor tells you to do so.

Other side effects

Common: may affect up to 1 in 10 people

- skin rash
- increased level of thyroid stimulating hormone in the blood

Uncommon: may affect up to 1 in 100 people

- feeling sick (nausea) or being sick (vomiting), occasionally with blood
- changes in liver function tests.
- diarrhoea

Rare: may affect up to 1 in 1,000 people

- liver problems such as liver inflammation

Very rare: may affect up to 1 in 10,000 people

- male infertility or erectile dysfunction
- enlargement of the breast in men as well as women
- general feeling of being unwell
- build up of fluid leading to swelling (oedema), particularly of your ankles
- high temperature (fever)
- lack of voluntary coordination of muscle movements (ataxia)
- feeling of weakness
- hair loss or discoloration
- blood in your urine (haematuria)
- a change in your normal bowel habit
- a change in taste
- Infections of the skin, including scalp
- severe reduction in white blood cells which makes infections more likely
- reduction in red blood cells which can make skin pale and causes weakness or breathlessness

- Occasionally Allopurinol tablets may affect your blood, which can manifest as bruising more easily than usual, or you may develop a sore throat or other signs of an infection. These effects usually occur in people with liver or kidney problems. Tell your doctor as soon as possible.
- feeling thirsty, tired and losing weight, these may be symptoms of diabetes. Your doctor may wish to measure the level of sugar in your blood to check if this is happening
- high levels of cholesterol in your blood (hyperlipidemia)
- depression
- headache, dizziness, drowsiness or disturbance of your vision
- muscles (paralysis) or loss of consciousness
- cataracts
- chest pain (angina), high blood pressure or a slow pulse
- weakness, numbness, unsteadiness on your feet, unable to move
- sensation of tingling, tickling, pricking or burning of skin (paraesthesia)
- stomatitis (Oral inflammation)

Not known: frequency cannot be estimated from the available data.

Aseptic meningitis (inflammation of the membranes that surround the brain and spinal cord): symptoms include neck stiffness, headache, nausea, fever or consciousness clouding. Seek medical attention immediately if these occur.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Allopurinol Tablets

Keep this medicine out of the sight and reach of children.

Do not store above 25°C. Store in the original package and keep containers tightly closed.

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Allopurinol Tablets contain

The **active** substance is Allopurinol. Each tablet contains 100mg of allopurinol. The **other** ingredients are Lactose monohydrate, Maize Starch, Povidone K30, Sodium Starch Glycollate and Magnesium Stearate (See Section 2 'Important information about some of the ingredients of Allopurinol tablets').

What Allopurinol Tablets look like and contents of the pack

Allopurinol Tablets are white, round, biconvex tablets embossed with MAL 100 on one side and plain on the reverse.

The product is available in containers of 1000, 500, 250, 100, 84, 70, 56, 42, 28, 21, 15 and 14 tablets. They are also available in blister packs of 84, 70, 56, 42, 28, 21, 15 and 14 tablets (not all pack sizes may be marketed).

Marketing Authorisation Holder

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Ares, Odyssey Business Park,
West End Road,
South Ruislip, HA4 6QD
United Kingdom

Manufacturer

Milpharm Limited,
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