

Do not use Allopurinol Tablets after the expiry date which is stated on the blister and the carton after EXP or EXP. DATE.
Keep Allopurinol Tablets out of the reach and sight of children.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything ask your doctor or pharmacist.

6. Contents of the pack and other information

What Allopurinol Tablets contain

1. The active substance in these tablets is allopurinol. They are available in 2 strengths of 100mg and 300 mg.
2. The other ingredients in your allopurinol tablets are lactose, soluble maize starch, polyvinyl pyrrolidone, croscarmellose sodium, colloidal silicone dioxide, magnesium stearate and water.

What Allopurinol Tablets look like and contents of the pack

Allopurinol Tablets 100mg and 300mg are white to off white, round biconvex tablets debossed with an ankh on one side and on the reverse face R1 (100mg tablets) or R2 (300mg tablets)

The 100mg tablets are supplied in boxes of 28 or 100 tablets and the 300mg tablets are supplied in boxes of 28 or 30 tablets.

Marketing Authorisation Holder and Manufacturer:

The Marketing Authorisation Holder for your tablets is:
RI Pharma Ltd, 6, St. John's Court, First Floor, Upper Forest Way, Swansea Enterprise Park, Swansea, SA6 8QQ

The manufacturers for your tablets are:

1. Pharmacare Premium Ltd., HHF003 Hal Far Industrial Estate, Birzebbugia, BBG 3000, Malta.
2. Wave Pharma Limited, 4th Floor Cavendish House, 369 Burnt Oak, Edgware, Middlesex, HA85AW, UK

If you would like this leaflet in a different format please contact the licence holder at the following address:
RI Pharma Ltd, 6, St. John's Court, First Floor, Upper Forest Way, Swansea Enterprise Park, Swansea, SA6 8QQ or email at info@ri-pharma.com

If you would like to have any further information or want to report any side effects, please email at info@ri-pharma.com

This leaflet was last revised in Jan 2017

POM

G1AGSL02AESRI



Package Leaflet: Information for the User ALLOPURINOL 100 mg AND 300 mg TABLETS 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. Do not pass it onto others. It may harm them, even if their symptoms 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 is and what it is 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 Tablet is and what it is used for

These tablets contain Allopurinol and are available in strengths of 100 mg and 300 mg. Allopurinol works by slowing down the speed of certain chemical reactions in your body. Allopurinol is used to treat high levels of uric acid in the body, which can cause gouty arthritis, skin and kidney problems. Some people may not get any symptoms.

Allopurinol is also used to prevent and treat kidney stones in patients who have high uric acid levels.

2. What you need to know before you take Allopurinol tablets:

Serious skin rashes (Hypersensitivity syndrome, Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported with the use of 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 aches (flu-like symptoms). The rash may progress to widespread blistering and peeling of the skin. These serious skin reactions can be more common in patients with chronic renal impairment and in people of Han Chinese or Thai origin. If you develop a rash or these skin symptoms, stop taking allopurinol and contact your doctor immediately.

Do not take Allopurinol Tablets:

- If you are allergic (hypersensitive) to Allopurinol or any of the other ingredients of these tablets (listed in section 6). The symptoms of an allergic reaction include itching, nettle rash, wheezing or swelling of the hands, throat, mouth or eyelids.
- During an attack of gout.

If you think any of the points above apply to you, do not take the tablets. Talk to your doctor first and follow the advice given.

Warnings and Precautions

Talk to your doctor or pharmacist before taking your medicine

- If you have kidney problems.
- If you suffer from high blood pressure or heart problems.
- If you are currently having an acute attack of gout.
- **If you suffer from hepatic or renal impairment.**
- If you suffer from rare inherited forms of galactose intolerance, the Lapp lactase deficiency or glucose-galactase malabsorption.
- If you suffer with conditions like Lesch-Nyhan syndrome or malignant disease where rate of urate formation is greatly increased.

Other medicines and Allopurinol tablets:

Tell your doctor or pharmacist if you are taking any of the following:

- Medicines to treat gout or other medicines to control uric acid levels e.g. probenecid.
- Anticoagulants – used to thin the blood e.g. warfarin.

- Chlorpromamide – used to control blood sugar levels.
- Aspirin or other salicylates.
- Immunosuppressive drugs such as mercaptopurine, azathioprine and cyclosporin.
- Anti-cancer drugs such as doxorubicin and bleomycin.
- Vidarabine – used to treat viruses such as herpes, chicken pox and shingles.
- Theophylline – used to treat breathing problems including asthma.
- Phenytoin – used to treat epilepsy.
- Medicines for heart problems or high blood pressure such as 'ACE inhibitors' or water tablets (diuretics).
- Ampicillin and amoxicillin – antibiotics.

Tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription

Taking Allopurinol tablets with food and drink

Take Allopurinol tablets with food and water.

Pregnancy and breast-feeding

If you are pregnant, trying to become pregnant or are breast feeding, ask your doctor or pharmacist for advice before taking allopurinol.

Driving and using machines

You may feel drowsy, giddy or have problems with your co-ordination. If this happens, do not drive or use any tools or machines.

3. How to take Allopurinol Tablets

Always take Allopurinol Tablets exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Taking this medicine

- Swallow the tablet with a drink of water.
- Take with or just after food.

Dosage in Adults

The usual starting dose in adults is between 100 mg and 300 mg a day taken as a single dose. The doctor may alter this dose depending on your response to treatment. The usual maintenance dose is between 200 mg and 600 mg a day, this dose may be split up and taken at separate times during the day.

Dosage in Children

For children the dose depends on the child's bodyweight and it is between 10 mg and 20 mg for each kg of bodyweight per day.

Dosage in the Elderly and in patients with kidney or liver problems

Patients with kidney or liver problems and the elderly may be prescribed a lower dose. The correct dose for you will be on the label.

Check the label and if you are not sure ask your doctor or pharmacist.

Sometimes, starting treatment with allopurinol can trigger an attack of gout. To prevent this, your doctor may prescribe another treatment for the first month.

Cancer treatment

Sometimes Allopurinol is used in patients with cancer to prevent problems due to high uric acid levels. In this case you should be given Allopurinol tablets before the cancer treatment begins.

If you take more Allopurinol Tablets than you should

An overdose of this medicine may be dangerous. If you have taken an overdose tell your doctor or go to the nearest hospital casualty department immediately.

If you forget to take Allopurinol Tablets

If you forget to take a dose take it as soon as you remember. But do not take two doses at the same time.

If you stop taking Allopurinol Tablets

Do not stop taking your Allopurinol tablet without talking to 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, these tablets can cause side effects, although not everybody gets them.

The following side effects may happen with Allopurinol Tablets:

Allergic reactions (affects less than 1 in 10,000 people).

If you have an allergic reaction, stop taking Allopurinol tablets and see a doctor straight away.

The signs may include:

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

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

If you experience any of the following, stop your tablets and tell your doctor as soon as possible:

Rare (affects less than 1 in 1000 people)

- Jaundice (yellowing of the skin and eyes)
- Joint pain or Painful swelling in your groin, neck or armpits
- Liver or kidney problems
- Nausea and vomiting (in some cases, blood may be present)
- Bleeding in the lips, eyes, mouth, nose or genitals
- Fever and chills, headache, aching muscles (flu-like symptoms) and generally feeling unwell
- Any changes to your skin, for example ulcers of the mouth, throat, nose, genitals and
- Conjunctivitis (red and swollen eyes), widespread blisters or peeling
- 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).

Very rare (affects less than 1 in 10,000 people)

- Bruising more easily than usual, or you may develop a sore throat or other signs of an infection. Tell your doctor as soon as possible. Occasionally Allopurinol tablets may affect your blood or lymph system. These effects usually occur in people with liver or kidney problems
- Blood in your urine (haematuria)
- High temperature
- High levels of cholesterol in your blood (hyperlipidaemia)
- Chest pain, high blood pressure or a slow pulse
- Weakness, numbness, unsteadiness on your feet, feeling unable to move muscles (paralysis) or loss of consciousness
- A general feeling of being unwell
- Headache, dizziness, drowsiness or disturbance of your vision
- Male infertility or erectile dysfunction
- Enlargement of the breasts, in men as well as women
- A change in taste
- A change in your normal bowel habit
- Cataracts
- Air loss or discolouration
- Depression
- Fits (convulsions)
- Build up of fluid leading to swelling (oedema) particularly of your ankles
- 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.

If any of the side effects gets 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. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme at www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Allopurinol Tablets

Store in a cool, dry place below 25°C in the original package. Do not put the tablets into another container as they might get mixed up. Keep them in the pack in which they are supplied.