

Title: Allopurinol Tablets Leaflet
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Pharmacode

Direction for Travel

Package Leaflet: Information for the User

Allopurinol 100mg, 200mg and 300mg 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 only. 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.

What is in this leaflet:

- What Allopurinol is and what it is used for
- What you need to know before you take Allopurinol
- How to take Allopurinol
- Possible side effects
- How to store Allopurinol
- Contents of the pack and other information

1. WHAT ALLOPURINOL IS AND WHAT IT IS USED FOR

Allopurinol tablets contain a medicine called allopurinol. 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 is 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.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ALLOPURINOL

Do not take Allopurinol if:

- you are allergic (hypersensitive) to allopurinol or any of the other ingredients of Allopurinol (listed in Section 6).

If you are not sure, talk to your doctor or pharmacist before taking Allopurinol.

Warnings and Precautions

Talk to your doctor or pharmacist before taking your medicine if:

- you are of Han Chinese, African or Indian origin
- 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.
- you have heart problems or high blood pressure and you take diuretics and/or a medicine called ACE-inhibitors.
- you are currently having an attack of gout.
- you have thyroid problems.

Take special care with Allopurinol:

- 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 to drink sufficiently to dilute your urine.

- 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

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

- aspirin
- theophylline, used for breathing problems
- medicines used for fits (epilepsy), phenytoin
- vidarabine, used to treat herpes or chickenpox
- antibiotics (ampicillin or amoxicillin)
- didanosine, used to treat HIV infection
- medicines used for cancer
- medicines used to reduce your immune response (immunosuppressants)
- medicines used to treat diabetes
- medicines for heart problems or high blood pressure such as ACE inhibitors or water tablets (diuretics)
- medicines used to thin your blood (anticoagulants), such as warfarin
- any other medicine to treat gout.

If aluminium hydroxide is taken concomitantly, allopurinol may have an attenuated effect. There should be an interval of at least 3 hours between taking both medicines.

With administration of allopurinol and cytostatics (e.g. cyclophosphamide, doxorubicin, bleomycin, procarbazine, alkyl halogenides), blood dyscrasias occur more frequently than when these active substances are administered alone. Blood count monitoring should therefore be performed at regular intervals.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription, including herbal medicines. This is because Allopurinol can affect the way some medicines work. Also some other medicines can affect the way Allopurinol works.

Pregnancy and breast-feeding

Talk to your doctor before taking this medicine if you are pregnant, might become pregnant or are breast-feeding. Allopurinol is excreted in the human breast milk. Allopurinol during breast-feeding is not recommended.

Driving and using machines

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

Allopurinol 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.

3. HOW TO TAKE ALLOPURINOL

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

Take the tablet after food and swallow it with a glass of water.

The recommended dose ranges from 100 to 900 mg each day. You will usually start on a low dose, which will be increased if necessary.

If you are an older person or if you have reduced liver or kidney function, your doctor may prescribe a lower dose or to take it at longer intervals. If you have dialysis two or three times a week, your doctor may prescribe a dose of 300 or 400 mg which is to be taken straight after your dialysis.

Use in children (under 15 years)

The usual dose ranges from 100 to 400 mg each day.

If you take more Allopurinol than you should

If you take more Allopurinol than you should,

150 mm

6 mm

8 mm

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contact a doctor or go to hospital straight away. Take the medicine pack with you. Signs of an overdose may include nausea, vomiting, diarrhoea and dizziness.

If you forget to take Allopurinol

If you forget a dose, take it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking Allopurinol

Do not stop taking your Allopurinol 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, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

Hypersensitivity

Uncommon (may affect less than 1 in 100 people)

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

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)
- abnormal liver tests.

Rare (may affect up to 1 in 1000 people)

- liver problems such as liver inflammation

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

- 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.
- Allopurinol may affect the lymph nodes
- high temperature
- blood in your urine (haematuria)
- high levels of cholesterol in your blood (hyperlipidaemia)
- a general feeling of being unwell or feeling weak
- weakness, numbness, unsteadiness on your feet, feeling unable to move muscles (paralysis) or loss of consciousness
- headache, dizziness, drowsiness or disturbance of your vision
- chest pain (angina), high blood pressure or a slow pulse
- male infertility or erectile dysfunction
- enlargement of the breasts, in men as well as women
- a change in your normal bowel habit
- a change in taste
- cataracts
- hair loss or discolouration
- depression
- lack of voluntary coordination of muscle movements (ataxia)
- sensation of tingling, tickling, pricking or burning of skin (paraesthesia)
- build up of fluid leading to swelling (oedema) particularly of your ankles

- abnormal glucose metabolism (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 or pharmacist. This includes any possible side effects not listed on this leaflet. You can also report side effects directly via the Yellow Card Scheme at: 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

- KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.
- This medicinal product does not require any special storage condition.
- Do not take after the expiry date shown on the packaging.
- REMEMBER this medicine was prescribed for you. You should not give it to anyone else even if you think their symptoms are similar.
- If you are told to stop taking this medicine, take any tablets which you haven't finished back to your pharmacist to be destroyed safely. Only keep the tablets if the doctor tells you to.
- 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.
- If the tablets show any signs of deterioration check with your pharmacist who will advise you what to do.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Allopurinol contains

- The active substance is Allopurinol.
- The tablets also contain Starch, Pregelatinised, Lactose Monohydrate, Crospovidone Type B, Povidone PVP K30, Isopropyl Alcohol, Crospovidone Type B Silica, Colloidal Anhydrous, and Magnesium Stearate.

What Allopurinol looks like and contents of the pack

Allopurinol Tablets contain 100, 200 or 300mg Allopurinol.

Each Allopurinol 100 mg tablet is white to off white colored, flat faced beveled edged, round tablets free from physical defects, debossed with "0" and "21" on either side of breakline and "100" on the other side. The breakline line is only to facilitate breaking for ease of swallowing and not to divide the tablet into equal doses.

Each Allopurinol 200 mg tablet is white to off white colored, biconvex, round tablets free from physical defects, debossed with "B2" on one side and plain on the other side.

Each Allopurinol 300 mg tablet is white to off white colored, flat faced beveled edged, round tablet, debossed with "300" and "020" on either side of breakline and plain on other side. The breakline is only to facilitate breaking for ease of swallowing and not to divide the tablet into equal doses.

The tablets are available as blister packs of 28, 56 or 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder RxFarma, Colonial Way, Watford, Hertfordshire, WD24 4YR.

Manufacturer

Rx Farma Limited, Unit 3, Colonial Way, Watford, Hertfordshire, WD24 4YR

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