

# Allopurinol 100mg and 300mg tablets

**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**
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### **1 What Allopurinol Tablets are and what they are 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 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 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 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. 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 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 can affect the way some medicines work. Also some other medicines can affect the way Allopurinol works.

In particular, tell your doctor 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.

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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 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 Tablets contain 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'.

## 4 How to take Allopurinol Tablets

Always take this medicine exactly as your doctor or pharmacist has told you. 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.

Your 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.

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 Tablets than you should

If you take more Allopurinol Tablets than you should, 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 Tablets

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.

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### If you stop taking Allopurinol Tablets

Do not stop taking your Allopurinol Tablets 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.

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

- serious potentially life-threatening allergic reaction
- itchy or flaky skin rash, blistered, peeling skin or sore lips and mouth
- serious allergic reaction which causes swelling of the face, lips, tongue or throat, or difficulty breathing or swallowing, severe boils
- changes in the amounts of blood cells (as seen in blood tests); causing increased bruising, nosebleeds, sore throats or infections
- fever, swollen lymph glands, joint pain, swollen blood vessels, yellowing of the skin or eyes and inflammation of the liver (hepatitis, including hepatic necrosis and granulomatous hepatitis), kidney damage (blood in the urine), or fits
- drug-induced hypersensitivity reaction that includes fever, rash and blood abnormalities (Drug rash with eosinophilia and systemic symptoms - **DRESS**)
- 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 and genitals or 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)
- itchy skin rash caused by allergic reaction – pale red irregular raised patches with severe itching (hives)
- potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported (see section 2).

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.

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**Uncommon** (may affect up to 1 in 100 people):

- feeling sick (nausea) or being sick (vomiting)
- diarrhoea.

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

- high temperature
- 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.

**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 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://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.

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## **5 How to store Allopurinol Tablets**

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

Store below 25°C in a dry place.

Do not use this medicine after the expiry date which is stated on the label/carton/bottle. 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 any 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 (the ingredient that makes the tablets work) is Allopurinol. Each tablet contains either 100mg or 300mg of the active ingredient.
- The other ingredients are maize starch, carmellose sodium, cellulose, sodium lauryl sulfate, lactose, magnesium stearate.

### **What Allopurinol Tablets look like and contents of the pack**

Allopurinol Tablets 100mg are white, circular, biconvex, uncoated tablets impressed "C" and the identifying letters "AD" on either side of a central division line on one face.

Allopurinol Tablets 300mg are white, circular, biconvex, uncoated tablets impressed with the identifying letters "AG" and "C" on either side of a central division line on one face.

Pack sizes are 28 tablets.

### **Marketing Authorisation Holder and Manufacturer**

Accord, Barnstaple, EX32 8NS, UK.

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