

**Package leaflet: Information for the User**  
**Allopurinol 100mg Tablets**  
**Allopurinol 300mg Tablets**  
Allopurinol

**Read all of this leaflet carefully before you start to take 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 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 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.

**Warnings and precautions**

**Talk to your doctor 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 each day. They will also monitor you closely

- if you have heart problems or high blood pressure and you take diuretics and/or medicines 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 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 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 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.

Allopurinol Tablets may affect or be affected by the following medicines:

- aspirin
- theophylline, used for breathing problems
- medicines used for fits (epilepsy), phenytoin and carbamazepine
- vidarabine, used to treat herpes or chickenpox
- antibiotics (ampicillin or amoxicillin)
- didanosine, used to treat HIV infection
- medicines used for cancer e.g. azathioprine, mercaptopurine, cyclophosphamide, capecitabine
- medicines used to reduce your immune response (immunosuppressants) e.g. ciclosporin
- medicines used to treat diabetes e.g. chlorpropamide
- 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 Tablets can affect the way some medicines work. Also some other medicines can affect the way Allopurinol Tablets works.

### **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**

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 and sodium**

- Lactose. If you have been told by your doctor that you have an intolerance to some sugars contact your doctor before taking this medicine.
- Sodium. This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

## **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.

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 3 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 (or anybody else, including a child), 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. However, if it is almost 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 Tablets**

Do not stop taking your allopurinol tablets without talking to your doctor.

If you have any further questions on the use of this medicine, 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 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)
- abnormal liver tests.

**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

- 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 Tablets 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
- vomiting blood
- greasy stools
- 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.
- increased urea, creatinine or other nitrogen-containing compounds in the blood (azotaemia).

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 national reporting systems listed below:

United Kingdom:

Yellow Card Scheme

Website: [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

Malta:

ADR Reporting,

Website: [www.medicinesauthority.gov.mt/adrportal](http://www.medicinesauthority.gov.mt/adrportal)

By reporting side effects you can help provide more information on the safety of this medicine.

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

Keep out of the sight and reach of children.

- Allopurinol Tablets should be stored in a cool, dry place. Store in the original container to protect it from light and do not transfer to another container.
- Allopurinol Tablets should not be taken after the expiry date on the label; the expiry date refers to the last day of the 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 ingredient is: allopurinol 100mg or 300mg. The other ingredients are: lactose, maize starch, povidone, sodium starch glycolate, magnesium stearate, water.

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

Allopurinol Tablets are supplied in plastic containers containing 100 tablets or blister packs of 28 or 56 tablets. Not all pack sizes may be marketed.

**Marketing Authorisation Holder:** Austin McNeil Ltd., 772 Fulham Road, London, England, SW6 5SJ

**Manufacturer:** CP Pharmaceuticals Ltd, Ash Road North, Wrexham, LL13 9UF, UK.

### **Other formats:**

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK Only).

Please be ready to give the following information:

Product name	Reference number
Allopurinol 100mg Tablets	PL 53797/0018
Allopurinol 300mg Tablets	PL 53797/0019

This is a service provided by the Royal National Institute of Blind People.

For Malta please call: +44 1978 661 261.

**This leaflet was last revised in 10/2021.**