

PACKAGE LEAFLET: INFORMATION FOR THE USER

Allopurinol 100mg 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 on to 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 are and what are they 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 are they used for

Allopurinol belongs to a group of medicines called enzyme inhibitors. These medicines inhibit the amount of uric acid production in your body.

Allopurinol 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 treat the following conditions:

- Gout (increased uric acid quantity in the body). The uric acid builds up in your joints and tendons as crystals causing an inflammatory reaction. The inflammation causes the skin around certain joints to become swollen, tender and sore when only slightly touched. You may also get severe pain when the joint is moved.
- Kidney stones formation and certain other types of kidney diseases due to increase in the amount of uric acid in the body
- Some types of Cancer due to increase in the amount of uric acid in the body
- Enzyme disorders due to increase in the amount of uric acid in the body

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 Allopurinol Tablets (see section 6)

Do not take Allopurinol tablets if the above applies to you. 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 kidneys or liver. Your doctor may give you a lower dose or ask you to take it less often than each day. They will monitor you more closely.
- you suffer from high blood pressure or have heart problems and you take diuretics and/or a medicine called ACE-inhibitors.
- you are currently having an attack of gout
- you have thyroid problems
- you suffer from rare inherited forms of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption. Allopurinol tablets contain a small amount of 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.**

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. If you develop a rash or these skin symptoms, **stop taking allopurinol and contact your doctor immediately.**
- 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 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

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.

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

- Aspirin
- medicines used to treat **high blood pressure** (ACE inhibitors e.g. captopril).
- medicines used to treat **bacterial infections** (antibiotics e.g. ampicillin and amoxicillin).
- medicines used to thin the **blood** (anticoagulants e.g. dicoumarol, phenprocoumon, warfarin).
- medicines used to treat **diabetes** (e.g. chlorpropamide and tolbutamide).
- medicines used to treat **epilepsy** (e.g. phenytoin, carbamazepine).
- medicines used for **chemotherapy** (e.g. azathioprine, mercaptopurine, cyclophosphamide).
- ciclosporin – a medicine used to suppress the immune system following organ transplant and in **immune related disorders**.
- theophylline – a medicine used in **asthma** and **breathing disorders**.
- thiazide diuretics – medicines used to get rid of excess fluid from the body and in **high blood pressure** such as ACE inhibitors or water tablets (diuretics).

- uricosurics – medicines that are used to reduce **uric acid levels** (e.g. probenecid, salicylate).
- vidarabine (adenine arabinoside) is an anti-viral drug which is used to treat **herpes simplex or chicken pox**.
- any other medicine to treat gout.
- didanosine used to treat **HIV infection**.
- 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.

Taking Allopurinol Tablets with food and drink

Allopurinol Tablets should be taken with food and water.

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 make some people feel drowsy, giddy or have problems with co-ordination. Do not drive or operate dangerous machinery if you are affected.

Allopurinol tablets contains lactose:

Allopurinol Tablets contains lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

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.

Swallow the tablet with a glass of water after meal.

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.

Adults (Over 18 years)

The initial dose is usually 100mg daily, after food, but this can be gradually increased over one to three weeks according to the levels of uric acid in your blood and urine. The following dosages are administered depending on the severity of the disease.

100mg to 200mg average daily dose for mild gout

300 to 600mg daily for moderately severe gout

700 to 900mg daily for severe gout.

Up to 300mg can be taken as a single dose; larger doses should be divided throughout the day.

Patients with liver disease:

Your dose may need to be reduced; this is determined by monitoring the levels of uric acid in your body.

Patients with kidney disease:

- You may be asked to take less than 100 mg each day
- or you may be asked to take single dose of 100 mg at longer intervals than one day.

If you are receiving frequent dialysis for kidney disease, then your dose may need to be adjusted or else a single dose of 300 to 400mg following dialysis may be given.

Elderly (Over 65 years):

Your doctor will prescribe a lower dose of Allopurinol tablets that best controls your symptoms.

Children under 15 years (for use in enzyme disorders and with chemotherapy)

The daily dose is calculated based on body weight and is usually 10 to 20 mg/Kg body weight.

The usual dose ranges from 100 to 400mg daily.

Treatment of high uric acid levels in chemotherapy:

Treatment commences from one to two days before chemotherapy and take 600 to 800mg daily in divided doses for 2 to 3 days.

The maintenance dose is then decided depending on your response to treatment.

While taking this medicine the dose of your chemotherapy may be reduced as this medicine can increase its effects.

Note: While you are taking allopurinol tablets your doctor may ask you to undergo regular blood tests to check your levels of uric acid and in some cases monitor your liver and kidney's function.

If you take more Allopurinol Tablets than you should

If you or someone else swallows several of these tablets all together, or if you think a child has swallowed any of these tablets, contact your doctor or pharmacist or hospital emergency department immediately. Always take any tablets left over with you, also the box and leaflet as this will allow easier identification of the tablets. Signs of an overdose may include nausea, vomiting, diarrhoea and dizziness.

If you forget to take Allopurinol Tablets

If you forget to take a dose, take it as soon as you remember. If it is almost time for your next dose, do not take the missed dose and just carry on as before. Do not take a double dose to make up for a forgotten dose.

If you stop taking Allopurinol Tablets

Keep taking the medicine for as long as your doctor has told you, even if you are feeling better. If you stop the medicine too soon, your condition may become worse again.

Do not stop taking your tablets without consulting 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 can cause side effects, although not everybody gets them. If you experience the following side effects seek immediate medical attention.

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 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.
- angioedema has been reported to occur with and without signs and symptoms of a more generalised hypersensitivity reaction such as red welts that suddenly appear, especially near the eyes and lips, but also on the hands, feet, and the inside of the throat, burning, painful, swollen, sometimes itchy areas, discoloured patches or rash on the hands, feet, face, or genitals
- vomiting blood (haematemesis)
- 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 (T cell lymphoma) with signs of red, rash like patches, raised patches (plagues), lumps
- loss of consciousness
- abnormal glucose metabolism (diabetes). Your doctor may wish to measure the level of sugar in your blood to check if this is happening.
- 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.
- diarrhoea

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

- furuncle/pimples
- 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)
- 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
- oily stools

Not known (cannot be established 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 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 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 Tablets

Do not store above 25°C. Store in the original package. Keep the container tightly closed.

Keep out of the sight and reach of children.

Do not use your tablets after the expiry date stated on the carton or label. The expiry date refers to the last day of that month

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.

6. Contents of the pack and other information

What Allopurinol Tablets contain

The **active** substance is Allopurinol.

The **other** ingredients are Lactose monohydrate, crospovidone, maize starch, povidone K-30 and magnesium stearate (*see section 2 for Important information about some of the ingredients of Allopurinol tablets*).

What Allopurinol Tablets look like and contents of the pack

Allopurinol 100 mg Tablets are white to off white, round, biconvex, uncoated, marked with "AW" on one side and plain on the other side.

Allopurinol 300 mg Tablets are white to off white, round, biconvex, uncoated, marked with "AX" on one side and plain on the other side.

Allopurinol tablets are available in container packs of 28, 100, 500 and 1000 tablets. They are also available in blister pack of 28 tablets (Not all pack sizes may be marketed).

Marketing Authorisation Holder and Manufacturer

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