

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Allopurinol 100 and 300 mg 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 is and what it is used for
2. What you need to know before you take Allopurinol
3. How to take Allopurinol
4. Possible side effects
5. How to store Allopurinol
6. Contents of the pack and other information

1 What Allopurinol is and what it is used for

Allopurinol belongs to a group of medicines called enzyme inhibitors. 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 uric acid build-up during some cancer treatments
- Gouty arthritis (a form of arthritis caused by deposits of uric acid) or gout (swelling of the joints caused by build-up of uric acid)
- Skin Tophi (deposit of urates causing lumps beneath the skin)
- Some types of kidney stones or kidney problems
- Lesch-Nyhan Syndrome, a rare hereditary disorder caused by a deficiency of the enzyme HPRT (hypoxanthine guanine phosphoribosyl transferase).

2 What you need to know before you take Allopurinol

Do not take Allopurinol if:

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

Warnings and precautions

Talk to your doctor before taking Allopurinol if:

- you are of Han Chinese, Thai or Korean 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. 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 rare, 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, have recently taken or might take any other medicines, including those obtained without a prescription. This includes herbal medicines.

Medicines which may interact with or be affected by Allopurinol:

- Medicines used to treat high blood pressure or heart problems such as ACE inhibitors or water tablets (diuretics, in particular thiazides)
- 6-Mercaptopurine (used to treat blood cancer)
- Azathioprine (used to suppress the immune system)

The co-administration of 6-mercaptopurine or azathioprine with allopurinol should be avoided. When 6-mercaptopurine or azathioprine is given concurrently with Allopurinol the dose of 6-mercaptopurine or azathioprine should be reduced because their activity will be prolonged. This could increase the risk of serious blood disorders. In this case, your doctor will closely monitor your blood count during treatment.

Seek medical advice immediately if you notice that you have any unexplained bruising, bleeding, fever or sore throat.

- Medicines used to treat cancer e.g. cyclophosphamide, doxorubicin, bleomycin, procarbazine, alkyl halogenides (cytostatics). Blood count monitoring should be performed at regular intervals
- Vidarabine, used to treat herpes or chickenpox
- Aspirin (Salicylates)
- Any other medicine to treat gout
- Chlorpropamide, used to treat diabetes
- Warfarin, used to help prevent blood clots (anticoagulants)
- Phenytoin, used to treat epilepsy
- Theophylline, used to treat asthma
- Antibiotics (Amoxicillin and Ampicillin)
- Ciclosporin, used to reduce immune response after organ transplant
- Didanosine, used to treat HIV infection. If concomitant use is unavoidable, a dose reduction of didanosine and close monitoring may be required
- Aluminium hydroxide. There should be an interval of at least 3 hours between taking both medicines.

Taking Allopurinol with food and drink

Take the tablet after food and swallow it with a glass of 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 for advice before taking this medicine.

Pregnancy

Allopurinol is not recommended for use during pregnancy unless you and your doctor have discussed the risk and benefits involved.

Breast-feeding

Allopurinol is not recommended if you are breast-feeding or planning to breast-feed as it passes into breast milk.

Driving and using machines

Allopurinol may cause drowsiness, dizziness, affect your co-ordination or make you sleepy. 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 medicine.

3 How to take Allopurinol

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

- Allopurinol may be taken orally once a day after a meal.
- Should the daily dosage exceed 300 mg and gastrointestinal disturbances occur, Allopurinol may need to be given in divided doses.

Adults

- 100 mg to 200 mg daily in mild conditions
- 300 mg to 600 mg daily in moderately severe conditions
- 700 mg to 900 mg daily in severe conditions
- If dosage based on bodyweight is required, 2 to 10 mg/kg bodyweight/day should be used

Kidney problems

If you have severe kidney problems, your doctor may prescribe less than 100 mg per day or tell you to take a single dose of 100 mg at longer intervals than one day.

If you have dialysis two or three times a week, your doctor may prescribe a dose of 300 mg – 400 mg immediately after dialysis (with none in the interim).

Liver problems

Reduced doses should be used in patients with liver impairment. Your doctor should arrange for you to have periodic liver function tests during the early stages of your treatment.

Elderly

Your doctor will prescribe the lowest dose that best control your symptoms.

Use in children

Children under 15 years: 10 to 20 mg/kg bodyweight/day up to a maximum of 400 mg daily.

Use in children is rare, except in certain conditions such as leukaemia and certain enzyme disorders such as Lesch-Nyhan syndrome.

If you take more Allopurinol than you should

If you accidentally take too many tablets, contact your doctor or nearest hospital emergency department **immediately** for advice. Remember to take this leaflet or any remaining tablets with you.

Symptoms of overdose include: Nausea, Vomiting, Diarrhoea, Dizziness.

If you forget to take Allopurinol

Take it as soon as you remember, unless it is time for your next dose. If you miss a 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 medicine, ask your doctor or pharmacist.

4 Possible side effects

Like all medicines, Allopurinol can cause side effects, although not everybody gets them.

Seek medical advice immediately if you develop the following symptoms:

- allergic reactions: swelling of the face, throat or tongue, difficulty breathing or dizziness (anaphylaxis)
- severe blistering of the skin, mouth, eyes and genitals (Stevens-Johnson syndrome, toxic epidermal necrolysis)
- swelling of the deeper layers of the skin caused by a build-up of fluid (angioedema)
- fever, general ill feeling, swollen/enlarged lymph nodes and skin eruption (Drug Rash with Eosinophilia and Systemic Symptoms (DRESS))
- serious inflammation of the linings of the brain (aseptic meningitis). Symptoms include neck stiffness, headache, nausea, fever or consciousness clouding
- loss of consciousness (coma).

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

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)

- skin abscesses caused by a bacterial infection
- severe reduction in blood cells/platelets which can cause weakness, bruising or make infections more likely
- fever
- blood in your urine (haematuria)
- high levels of cholesterol in your blood (hyperlipidaemia)
- a general feeling of being unwell or feeling weak (malaise)
- 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 (hypertension) or a slower heartbeat (bradycardia)
- male infertility or erectile dysfunction
- enlargement of the breasts in men (gynaecomastia)
- a change in normal bowel habit
- a change in taste, inflammation of the mouth
- visual impairment, cloudy patches in the lens of the eye, causing blurred vision (cataracts)
- hair loss or discolouration
- depression
- lack of voluntary co-ordination of muscle movements (ataxia)
- disorders of the nervous system e.g. "creeping" sensation and other sensory disorders affecting hands &/or feet (peripheral neuropathy)
- tingling or numbness in the hands or feet (paraesthesia)
- A sensation of whirling and loss of balance, feeling dizzy or giddy (vertigo)
- high blood sugar (diabetes). Your doctor may wish to measure your blood sugar level.

Not known (cannot be estimated from available data)

- Lichenoid skin rash (itchy reddish-purple skin rash and/or threadlike white-grey lines on mucous membranes).

If any of the side-effect 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

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the container/blister pack after EXP. The expiry date refers to the last day of that month.
- Do not store above 25°C. Store in the original packaging.

- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6 Contents of the pack and other information

What Allopurinol contains:

- Each 100 mg tablet contains 100 mg of Allopurinol
- Each 300 mg tablet contains 300 mg of Allopurinol

The other ingredients are: Lactose, Maize Starch, Povidone, Crospovidone and Magnesium Stearate.

What Allopurinol Tablets looks like and contents of the pack:

- Allopurinol 100 mg are white, circular, biconvex tablets with “100” on one face and plain on the reverse.
- Allopurinol 300 mg are white, circular, biconvex tablets with “300” on one face and plain on the reverse.

Allopurinol is available in:

Allopurinol tablets are available in:

- Securitainer: 28, 100, 500 or 1000 tablets
- Blister pack: 28 tablets.

Not all pack sizes may be marketed.

Product Licence Numbers:

- Allopurinol 100 mg Tablets: PL 11311/0707
- Allopurinol 300 mg Tablets: PL 11311/0708

Marketing Authorisation Holder:

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220 Butterfield
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