Package leaflet: Information for the user

Allopurinol 100mg Tablets
Allopurinol 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, pharmacist or nurse.
- The 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, pharmacist or nurse. 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
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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 tablets are 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 allopurinol tablets (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, Thai, Korean 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:

- Severe 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 or have recently taken or might take any other medicines especially 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.

It is especially important to tell your doctor if you are taking any of the medicines listed below. Your doctor may need to reduce the dose of your medicine and/or monitor you more carefully because of the increased risk of side effects when allopurinol tablets is taken at the same time as:

- 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.

Allopurinol with food, drink and alcohol

Take the tablet after food with a glass of water

Pregnancy, breast-feeding and fertility

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:

If you have been told by your doctor that you have intolerance to some sugars contact your doctor before taking this medicinal product.

For Allopurinol 300mg Tablets

Information on sodium content

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. 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.

You 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.

Doses:

Adults:

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.

Children (under 15 years):

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

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Elderly or patients with kidney disease:
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.

If you take more Allopurinol tablets than you should
- If you take more of this medicine 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.

If you stop taking Allopurinol Tablets
- Do not suddenly stop taking these tablets without talking to your doctor. Your symptoms may recur if you stop taking them suddenly. Treatment should continue for as long as your doctor feels it is needed. If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

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, stop your tablets and tell your doctor immediately:**

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

Not known (cannot be estimated from 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.

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

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 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.

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).

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 Website: www.mhra.gov.uk/yellowcard or search for the MHRA Yellow card in 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

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date (EXP.) which is stated on the carton or label. The expiry date refers to the last day of that month.
- Securitainers: Store in a cool, dry place and protect from light.
- Blister packs: Do not store above 25^{0}C. Keep the blister in the outer carton to protect from light and moisture.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. This measures will help protect the environment.

6. Contents of the pack and other information

What Allopurinol tablets contains
- The active ingredient is allopurinol.
- The other ingredients are: lactose, maize starch, povidone and magnesium stearate. The 300mg tablets also contain sodium starch glycolate.

What Allopurinol tablets look like and contents of the pack
- Allopurinol 100mg tablets are white, round, biconvex, uncoated tablets marked with '100' on one face and 'BL' on the other.
- Allopurinol 300mg tablets are white, round, biconvex, uncoated tablets marked with '300' on one face and 'BL' on the other.
- Allopurinol 100mg Tablets come in packs of 28, 30, 56, 60, 84, 90 and 250
- Allopurinol 300mg Tablets come in packs of 28, 30, 56, 60 and 100
- Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Name and address: Bristol Laboratories Ltd,
Unit 3, Canalside, Northbridge Road, Berkhamsted,
Hertfordshire, HP4 1EG, United Kingdom
Telephone: 0044 (0)1442 200922
Fax: 0044 (0)1442 873717
Email: info@bristol-labs.co.uk

Manufacturer
Bristol Laboratories Ltd
Laporte Way, Luton, LU4 8WL, United Kingdom

Manufacturer
Bristol Laboratories Limited
Unit 5, Traynor Way, Whitehouse Business Park,
Peterlee, SR8 2RU, United Kingdom

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