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
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

What Allopurinol tablets are and what they are used for

Allopurinol tablets are used in:
- the management of gout and other conditions associated with too much uric acid in the body, such as kidney disease, metabolic disorders, certain skin diseases, cancer and treatment with diuretics ("water tablets").
- certain types of kidney stones.

What you need to know before you take Allopurinol tablets

Do not take Allopurinol tablets and tell your doctor if you:
- are allergic to Allopurinol tablets or any of the other ingredients of this medicine (listed in section 6).
- are currently suffering from an acute attack of gout.

Warnings and precautions:

Talk to your doctor or pharmacist before using Allopurinol tablets if you:
- have severe liver or kidney disease or kidney problems, you may be given a lower dose.
- have a condition which causes increased levels of urate in the body (eg Lesch-Nyhan syndrome).
- have kidney stones, the kidney stones will become smaller and may enter your urinary tract.
- have heart problems or high blood pressure and you take diuretics and/or medicines called ACE-inhibitors.
- are currently having an attack of gout.
- have thyroid problems.

Possible side effects

Some side effects of this medicine are very rare (may affect less than 1 in 10,000 users).

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 and genitalia or 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 blisters 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.

Other medicines and Allopurinol tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, especially:
- asazololp (to treat rheumatoid arthritis and after organ transplants)
- with administration of allopurinol and medicines used to treat leukaemias and some cancers (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
- 6 mercaptopurine (used to treat some cancers and bowel diseases)
- adenine arabinoside
- probenecid (used in gout)
- phenytoin (used in epilepsy)
- theophylline (to treat asthma)
- ampicillin or amoxicillin (antibiotics)
- chlorpropamide (used in diabetes)
- didanosine (antiretroviral)
- diuretics (water tablets) or ACE inhibitors such as captopril (used in high blood pressure)
- 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.

Driving and using machines

Allopurinol tablets may make you feel dizzy, affect your co-ordination or make you sleepy. Make sure you are not affected before you drive or operate machinery.

Allopurinol tablets contain lactose

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

You should swallow the tablets with a little water after meals, if possible.

Drink plenty of fluids while you are on this medicine. Before starting treatment with allopurinol your doctor may give you an anti-inflammatory drug or colchicine, this helps prevent you getting acute gout attacks. If you are taking allopurinol for cancer then treatment with allopurinol will begin before treatment with cancer drugs.

Doses:

Adults: The recommended starting dose is 100-300mg once a day, this may be increased to 200-600mg a day in divided doses. A maximum dose of over 900mg a day is rarely needed.

Children under 15 years old (usually restricted to metabolic disease or cancer): 10-20mg per kg of body weight, up to a maximum of 400mg a day.

Elderly or patients with kidney or liver disease: Your doctor may prescribe a smaller dose.

If you take more Allopurinol tablets than you should:

If you (or someone else) swallow a lot of the tablets at the same time, or if you think a child has swallowed any of the tablets, contact your nearest hospital casualty department or tell your doctor immediately. Signs of an overdose may include feeling or being sick, diarrhoea, dizziness, headache, drowsiness and abdominal pain.

If you forget to take Allopurinol tablets:

Do not take a double dose to make up for a forgotten dose. If you forget to take a dose, take it as soon as you remember it and then take the next dose at the right time.

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 allergic reactions: swelling due to a reaction to the medicine:
  - rash
  - itchy skin rash caused by allergic reaction – pale red irregular raised patches with severe itching (hives)
  - multi-organ sensitivity disorder (Drug rash with eosinophilia and systemic symptoms - DRESS)
  - fever, 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)
  - very rare: rash caused by allergic reaction – pale red irregular raised patches with severe itching (lives)
  - potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported (see section 2).

Tell your doctor if you notice any of the following side effects or notice any other effects not listed:

Common (may affect up to 1 in 10 people):
- rash
- increased level of thyroid stimulating hormone in the blood.

Uncommon (may affect up to 1 in 100 people):
- feeling or being sick (occasionally with blood)
- changes in liver function tests.

Very rare (may affect up to 1 in 10,000 people):
- lack of muscle control/coordination, difficulty controlling muscles, weakness or loss of strength, numbness, ‘pins and needles’, ‘spinning’ sensation, unable to move muscles (paralysis), drowsiness, loss of consciousness
- feeling thirsty, tired and losing weight; these may be signs of diabetes, taste changes, building up of fluid leading to swelling (oedema)
- high levels of cholesterol in the blood (hyperlipidaemia)
- depression
- hair loss, discoulouration of hair
- catatras, changes in vision
- a change in bowel habit, inflammation of the mouth, vomiting blood
- pal, bulky, greyish, offensive stools due to increased amount of fat in the faeces (steatorrhea)
- high temperature, headache
- high blood pressure
- enlarged breasts in men and women, difficulty maintaining erection, infertility
- chest pain (angina), slow heart beat
- high levels of urea, nitrogen or creatinine in the blood due to kidney failure
- 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.

Not known:
- frequency cannot be estimated from the available data:
  - worsening of gout, dizziness, diarrhoea, stomach pain, kidney stones, ‘wet dreams’, joint pain, inflammation of blood vessels (causing rash, fever, sweating, fatigue and weight loss).

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 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

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 dispose of 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 are circular, biconvex, white, uncoated tablets. Pack sizes are 28 tablets.

Marketing Authorisation Holder and Manufacturer

Actavis, Barnstaple, EX32 8NS, UK.

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