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Allopurinol 100mg & 300mg Tablets (POM)

Leaflet Size : 280 (L) x 260 (W) mm

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- lack of voluntary coordination of muscle movements (ataxia)
- sensation of tingling, tickling, pricking or burning of skin (paraesthesia)

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.

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. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store www.mhra.gov.uk/yellowcard. By reporting side effect you can help provide more information on the safety of this medicine.

5. HOW TO STORE ALLOPURINOL TABLETS

Store in a cool, dry place below 25°C in the original package. Do not put the tablets into another container as they might get mixed up. Keep them in the pack in which they are supplied.

Do not use Allopurinol Tablets after the expiry date which is stated on the blister and the carton after EXP or EXP. DATE. The expiry date refers to the last day of that month.

Keep this medicine out of the reach and sight of children.

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 in these tablets is allopurinol. They are available in 2 strengths of 100mg and 300 mg.
- The other ingredients in your allopurinol tablets are lactose, soluble starch, maize starch, polyvinyl pyrrolidone, croscarmellose sodium, colloidal silicone dioxide, magnesium stearate and purified water

What Allopurinol Tablets look like and contents of the pack

Allopurinol Tablets 100mg and 300mg are white to off white, round biconvex tablets debossed with an ankh on one side and on the reverse face R1 (100mg tablets) or R2 (300mg tablets)

The 100mg tablets are supplied in boxes of 28 or 100 tablets and the 300mg tablets are supplied in boxes of 28 or 30 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder

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Manufacturer

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If you would like this leaflet in a different format, please contact the Marketing authorisation holder as listed above.

Product licence numbers

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POM

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- 4 -

PACKAGE LEAFLET: INFORMATION FOR THE USER

ALLOPURINOL 100mg and 300mg Tablets

Allopurinol

PHARMA CODE

XXXX
Pharmacode Reading Direction

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. Do not pass it onto 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 tablet is and what it is 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 TABLET IS AND WHAT IT IS USED FOR

These tablets contain Allopurinol and are available in strengths of 100mg and 300mg. 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 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 (hypersensitive) to Allopurinol or any of the other ingredients of these tablets (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 or pharmacist before taking your medicine

- If you are of Han Chinese, African or Indian origin.
- If you have liver or kidney problems. 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.
- If you suffer from high blood pressure or heart problems and you take diuretics and/or a medicine called ACE-inhibitors.
- If you are currently having an attack of gout.
- If you have thyroid problems.

Take special care with Allopurinol:

- 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 or 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.

- 1 -

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Other medicines and Allopurinol tablets:

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

- Any other medicine to treat gout.
- Anticoagulants – used to thin the blood e.g. warfarin.
- Aspirin or other salicylates.
- Medicines used to reduce your immune response (immunosuppressants).
- Anti-cancer drugs such as doxorubicin and bleomycin.
- Vidarabine – used to treat viruses such as herpes or chicken pox.
- Theophylline – used to treat breathing problems including asthma.
- Medicines used to treat diabetes.
- Medicines for heart problems or high blood pressure such as 'ACE inhibitors' or water tablets (diuretics).
- Medicines used for fits (epilepsy), phenytoin.
- Ampicillin and amoxicillin – antibiotics.
- 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.
- Didanosine, used to treat HIV infection.

Tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

This is because Allopurinol can affect the way some medicines work. Also some other medicines can affect the way Allopurinol works.

Taking Allopurinol tablets with food and drink

Take Allopurinol tablets with food and water.

Pregnancy and breast-feeding

If you are pregnant, trying to become pregnant or are breast feeding, ask your doctor or pharmacist for advice before taking allopurinol. Allopurinol is excreted in the human breast milk. Allopurinol during breast-feeding is not recommended.

Driving and using machines

You may feel drowsy, giddy or have problems with your co-ordination. If this happens, do not drive or use any tools or machines.

Allopurinol tablet contains lactose

If you have been told you have an intolerance to some sugars, contact your doctor before taking this medicine, as it contains lactose.

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.

Taking this medicine

Take the tablet after food and swallow it with a glass of water.

The recommended dose ranges from 100 to 900 mg each day.

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.

Dosage in Children (under 15 years)

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

Dosage in the Elderly and in patients with kidney or liver problems

Patients with kidney or liver problems and the elderly may be prescribed a lower dose or to take dose at longer intervals. The correct dose for you will be on the label.

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.

Check the label and if you are not sure ask your doctor or pharmacist.

If you take more Allopurinol Tablets than you should

If you take more Allopurinol 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 to take a dose take it as soon as you remember. 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 stop taking your Allopurinol tablet without talking to 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, these tablets can cause side effects, although not everybody gets them. The following side effects may happen with Allopurinol Tablets:

Hypersensitivity

Uncommon (may affect less than 1 in 100 people)

If you have a hypersensitivity (allergic) reaction, stop taking Allopurinol 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 (affects 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)

- Increased level of thyroid stimulating hormone in the blood.
- skin rash

Uncommon (may affect up to 1 in 100 people)

- feeling sick (nausea) or being sick (vomiting)
- abnormal liver tests.
- diarrhoea.

Rare (affects less than 1 in 1000 people)

- liver problems such as liver inflammation

Very rare (affects less than 1 in 10,000 people)

- Allopurinol may affect the lymph nodes
- Blood in your urine (haematuria)
- High temperature
- High levels of cholesterol in your blood (hyperlipidaemia)
- Chest pain (angina), high blood pressure or a slow pulse
- Weakness, numbness, unsteadiness on your feet, feeling unable to move muscles (paralysis) or loss of consciousness
- A general feeling of being unwell or feeling weak
- Headache, dizziness, drowsiness or disturbance of your vision
- Male infertility or erectile dysfunction
- Enlargement of the breasts, in men as well as women
- A change in taste
- A change in your normal bowel habit
- Cataracts
- Hair loss or discolouration
- Depression
- 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.
- 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.

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