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Package Leaflet: Information for the User

Allopurinol Tablets BP 300mg (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 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.

What is in this leaflet:

1. What Allopurinol Tablets 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 Tablets is and what it is used for

Allopurinol Tablets contain the active substance 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.

- to treat certain enzyme disorders, in particular Lesch-Nyhan syndrome.

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 (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 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 Allopurinol Tablets.

Take special care with Allopurinol Tablets:

- Serious 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 Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take 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 work.

- 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 (6-mercaptopurine)
- medicines used to reduce your immune response (immunosuppressants) e.g. azathiopine, ciclosporin
- medicines used to treat diabetes e.g. chlorpropamide
- 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 e.g. probenecid

If aluminium hydroxide is taken at the same time, this may weaken the effect of allopurinol. 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.

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.

Pregnancy and breast-feeding

Talk to your doctor before taking this medicine if you are pregnant, might become pregnant or are breast-feeding. 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 contains 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.

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

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. 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.

200 mm

400 mm

9.2 mm

16 mm

9.2 mm

200 mm

33.33 mm

166.65 mm

9.2 mm

16 mm

9.2 mm

150 mm

■ Black

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.

Use in children (under 15 years)

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

If you take more Allopurinol Tablets than you should

If you take more Allopurinol Tablets 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 stop taking your Allopurinol Tablets 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, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

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.

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)

- 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 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 Tablets 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):

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: Yellow Card Scheme, Website:

www.mhra.gov.uk/yellowcard. 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 store above 25°C. Store in the original package and keep containers tightly closed.

Do not use this medicine after the expiry date which is stated on the carton. 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 throw away 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 is Allopurinol. Each tablet contains 300mg of allopurinol. The other ingredients are Lactose monohydrate, Maize Starch, Povidone K30, Sodium Starch Glycollate and Magnesium Stearate (See Section 2 'Important information about some of the ingredients of Allopurinol tablets').

What Allopurinol Tablets look like and contents of the pack

Allopurinol Tablets are white, round, biconvex tablets embossed with MAL 300 on one side and plain on the reverse.

The product is available in containers of 1000, 500, 250, 100, 84, 70, 56, 42, 28, 21, 15 and 14 tablets. They are also available in blister packs of 84, 70, 56, 42, 28, 21, 15 and 14 tablets (not all pack sizes may be marketed).

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