

Package leaflet: Information for the user
Allopurinol 100 mg and 300 mg 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 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**
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1. What Allopurinol is and what it is used for

Allopurinol belongs to a group of medicines called enzyme inhibitors. Allopurinol lowers the amount of uric acid in the body. 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 diuretic (“water tablets”).
- certain types of kidney stones.

2. What you need to know before you take Allopurinol

Do not take Allopurinol tablets:

- if you are **allergic** to Allopurinol or any of the other ingredients of this medicine (listed in section 6).
- if you are currently suffering from an acute **attack of gout**.

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 Allopurinol tablets if;

- you are suffering, or have you suffered, from liver or kidney disease you are taking medicines (diuretics and/or a medicine called ACE inhibitors) for heart disease or high blood pressure
- you are currently having an attack of gout.
- you are of Han Chinese, African or Indian origin
- you have thyroid problems.

Take special care with Allopurinol

- if you have kidney stones, the kidney stones will become smaller and may have a small chance of entering and blocking your urinary tract.
- skin rashes 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.

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 any other medicines, including medicines obtained without a prescription.

Especially:

- azathioprine (to treat rheumatoid arthritis and after organ transplants)
- ciclosporin (to treat psoriasis, rheumatoid arthritis or after organ transplants)
- 6-mercaptopurine (used to treat some cancers and bowel diseases)
- adenine arabinoside (vidarabine), an anti-viral drug used to treat herpes or chickenpox
- probenecid (used to treat gout)
- phenytoin (used in epilepsy)
- theophylline (used to treat asthma)
- ampicillin or amoxicillin (antibiotics)
- aspirin or related medicines (salicylates)
- drugs to prevent the blood from clotting (such as warfarin)
- chlorpropamide (used in diabetes)
- didanosine (an anti-viral drug used to treat HIV)
- medicines for heart problems or high blood pressure such as ACE inhibitors or water tablets (diuretics) chemotherapy drugs such as cyclophosphamide, doxorubicin, bleomycin, procarbazine and meochlorethamine
- indigestion remedies (should not be taken within 3 hours of taking allopurinol)
- 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.
- medicines used to reduce your immune response (immunosuppressants)

Pregnancy and breast-feeding

If you are pregnant, planning to become 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. Do not drive or use any tools or machines until you know how it affects you.

Allopurinol contains lactose

This medicinal product 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 described in this leaflet, or 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.

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.

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.

The recommended dose is:

Adults

Starting dose of 100-300 mg once a day. This may be increased to 200-600 mg a day. Doses greater than 300 mg should be given in divided doses. A maximum dose of over 900 mg a day is rarely needed.

Children (usually restricted to metabolic disease or cancer):

10-20 mg per kg of body weight a day. The usual dose ranges from 100 to 400 mg each day.

Elderly or patients with kidney disease:

Your doctor may prescribe a smaller dose.

If you take more Allopurinol 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.

If you forget to take Allopurinol

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.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

If you stop taking Allopurinol

Do not stop taking your Allopurinol without talking to your doctor.

4. Possible side effects

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

You should stop taking Allopurinol and see your doctor immediately if the following symptoms occur.

Uncommon (may affect up to 1 in 100 people)

- a reaction of any kind such as flaking skin, boils or sore lips and mouth
- or very rarely, sudden wheeziness, fluttering or tightness in the chest; collapse

Rare (may affect up to 1 in 1,000 people)

- fever and chills, headache, aching muscles (flu-like symptoms) and generally feeling unwell
- bleeding in the lips, eyes, mouth, nose or genitals.
- any changes to your skin, for example; ulcers of the mouth, throat, nose, genitals and 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
- serious hypersensitivity reactions involving fever, skin rash, joint pain, abnormalities in blood and liver function tests (these may be signs of a multi-organ sensitivity disorder).

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.**

Other possible 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

- Vomiting
- Nausea
- Diarrhoea
- Abdominal pain
- Abnormal liver tests.

Rare: may affect up to 1 in 1,000 people

- Liver problems such as liver inflammation (hepatitis)
- Vasculitis (disorders that destroy blood vessels by inflammation)
- Erythema multiforme (hypersensitive reaction)
- Joint pain (arthralgia)
- Gout
- Nephrolithiasis (kidney stones)
- Changes in the number of white blood cells

Very rare: may affect up to 1 in 10,000 people

- high temperature (fever)
- blood in urine (haematuria)
- high levels of cholesterol in your blood (hyperlipidaemia)
- weakness, numbness, unsteadiness on your feet, feeling unable to move muscles (paralysis) or loss of consciousness
- headache, drowsiness or disturbance of vision
- chest pain (angina), high blood pressure or a slow pulse
- abnormal glucose metabolism (diabetes). Your doctor may wish to measure the level of sugar in your blood to help to decide if this is happening.
- change in taste perception (paragesia)
- sensation of tingling, tickling, pricking or burning of skin (paraesthesia)
- Furunculosis (a skin condition characterized by the development of recurring boils)

- Haemolytic anaemia (abnormal breakdown of red blood cells)
- Enlarged lymph nodes with anaemia and enlarged liver and spleen
- Coma
- Paralysis
- Cataract, Visual disorder
- Macular changes
- Vertigo
- Vomiting blood (haematemesis)
- Stomatitis (inflammation of the oral mucosa)
- Hair loss (alopecia)
- Discoloured hair
- Infertility, Erectile dysfunction
- Gynaecomastia (breast enlargements in males and women)
- A general feeling of being unwell or feeling weak
- A change in your normal bowel habit
- Fatty stools (steatorrhoea)
- Depression
- Lack of voluntary coordination of muscle movements (ataxia)
- retention of fluid leading to swelling (oedema) particularly of your ankles
- Angioedema (swelling below the skin)
- Decreased number of white blood cells
- Decreased number of platelets (thrombocytopenia)
- Aplastic anaemia (damage to the bone marrow which means that not enough new blood cells are produced)
- Malignancy that affects the lymphatic system (angioimmunoblastic T-cell lymphoma)
- Peripheral neuropathy
- Skin rash (drug eruption)
- Increased urea in blood (uremia)
- Increased nitrogen in blood (azotemia)

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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA

Pharmacovigilance, Website: www.hpra.ie.

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.

Store below 25°C in a dry place. Store in the original package in order to protect from moisture.

Do not use this medicine after the abbreviation 'EXP' stated on the carton and blister or the label. 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 contains

- The active ingredient is Allopurinol. Each tablet contains either 100 mg or 300 mg of the active ingredient.
- The other ingredients are croscarmellose sodium, powdered cellulose, lactose monohydrate, magnesium stearate, maize starch, sodium laurilsulfate, pregelatinised maize starch.

What Allopurinol looks like and contents of the pack

Allopurinol tablets are circular, biconvex, white, uncoated tablets.

Allopurinol tablets may be packed in:

- polypropylene or polyethylene containers with polyfoam wad or polyethylene filler and snap-on polyethylene lids or
- amber glass containers with screw caps and polyfoam wad or cotton wool or
- blister packs (PVC or Aluminium/PVC/PVdC).

Pack sizes: 10, 14, 20, 28, 30, 49, 50, 60, 98 or 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacture

MA Holder

Accord Healthcare Ireland Ltd, Euro House, Euro Business Park, Little Island, Cork T45 K857, Ireland

Manufacturer

Accord Healthcare Polska Sp. z o.o.,
Ul. Lutomiarska 50,95-200 Pabianice,
Poland

Accord UK Limited,
Whiddon Valley, Barnstaple, EX32 8NS, UK

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