

Package leaflet: Information for the patient

Allopurinol 100 mg tablets Allopurinol 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
4. Possible side effects
5. How to store Allopurinol
6. Contents of the pack and other information

1. What Allopurinol is and what it is used for

Allopurinol contains the active substance allopurinol. This medicine belongs to a group of medicines called enzyme inhibitors, which control the speed at which certain chemical changes occur in your body.

Allopurinol is used to treat conditions where too much uric acid is produced by your body such as: gout; certain types of kidney disease and kidney stones; cancer and some enzyme disorders which lead to the build-up of too much uric acid.

2. What you need to know before you take Allopurinol

Do not take Allopurinol:

- if you are allergic to allopurinol or any of the other ingredients of this medicine (listed in section 6).

If you are not sure, check with your doctor first before taking the medicine.

Warnings and precautions

Talk to your doctor or pharmacist before taking Allopurinol 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 experiencing an acute attack of gout
- you are of Han Chinese, Thai or Korean 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
- 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 ensure to drink sufficiently to dilute your urine.

Children and adolescents

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, have recently taken or might take any other medicines.

- medicines used to reduce your immune response (immunosuppressants) e.g. 6-mercaptopurine, azathioprine and cyclosporin
- adenine arabinoside (vidarabine), used to treat herpes or chickenpox
- other medicines to treat gout, such as probenecid
- acetylsalicylic acid (or related medicines called salicylates)
- chlorpropamide, used to treat diabetes
- medicines which thin the blood (anticoagulants), such as warfarin
- medicines used for fits (epilepsy), phenytoin
- theophylline, used for breathing problems
- antibiotics (ampicillin or amoxicillin)
- medicines used for the treatment of cancer
- didanosine, used to treat HIV infection
- medicines for heart problems or high blood pressure such as ACE inhibitors or water tablets (diuretics).
- aluminium hydroxide, as it may reduce the effect of allopurinol. There should be an interval of at least 3 hours between taking both medicines.
- With administration of Allopurinol and cytotoxic medicines (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.

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.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you might 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

Allopurinol may make some people drowsy or have problems with their coordination. Do not drive or operate machinery until you know how it affects you.

Allopurinol contains lactose

This medicine contains lactose (a type of sugar). 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 your doctor has told you. Check with your doctor if you are not sure.

The amount of Allopurinol that people can take can be very different. Your doctor will decide on a dose of Allopurinol that is right for you.

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.

The usual starting dose is in the range 100 to 300 mg daily, which may be taken as a single dose, after a meal. The dose may be increased up to 900 mg daily, depending on the severity of your condition.

If you are taking a daily dose higher than 300 mg, your doctor may tell you to divide the total dose into smaller doses spaced evenly throughout the day to reduce the risk of gastrointestinal side effects .

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.

Use in children and adolescents

Children and adolescents under 15 years: 10 to 20 mg/kg bodyweight/day up to a maximum of 400 mg daily in three divided doses. Use in children is rarely indicated, except in malignant conditions (especially leukaemia) and certain enzyme disorders such as Lesch-Nyhan syndrome.

Method of administration

Allopurinol is for oral use.

The tablets should be taken with a glass of water to make swallowing easier.

You should take your tablets after a meal to reduce the risk of side effects such as nausea (feeling sick) and vomiting.

If you take more Allopurinol than you should

If you take too many tablets or someone else takes your medicine by mistake, tell your doctor at once or go to the 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

If you forget to take a dose, take another one 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 the forgotten.

If you stop taking Allopurinol

Do not stop taking your Allopurinol unless your doctor tells you to.

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

4. Possible side effects

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

Hypersensitivity

Uncommon (may affect up to 1 in 100 people)

Check with your doctor **immediately** if you experience any of the following:

- 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
- 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)
- 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

These symptoms may mean that you are allergic to Allopurinol. 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 1,000 people)

- Liver problems such as liver inflammation

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

- 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 vision
- chest pain (angina), high blood pressure or a slow pulse

- retention of fluid leading to swelling (oedema) particularly of the ankles
- 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
- 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 may affect the lymph nodes
- male infertility, impotence
- enlargement of the breasts, in men as well as women
- a change in your normal bowel habit
- change in taste perception
- cataracts
- hair loss or discolouration
- depression
- lack of voluntary coordination of muscle movements (ataxia)
- sensation of tingling, tickling, pricking or burning of skin (paraesthesia)

Not known (frequency cannot be estimated from the 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.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

HPRRA 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.

Do not use this medicine after the expiry date which is stated on the blister and the carton. The expiry date refers to the last day of that month.

Store below 30°C.

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 substance is allopurinol

Allopurinol 100 mg: Each tablet contains 100 mg Allopurinol.

Allopurinol 300 mg: Each tablet contains 300 mg Allopurinol.

The other ingredients are:

Lactose monohydrate, crospovidone Type B, maize starch, povidone K 30 and magnesium stearate.

What Allopurinol looks like and contents of the pack

Allopurinol 100 mg is White to off white, round, biconvex, uncoated tablet with inscription "AW" on one side and plain on the other side having approximate diameter of 8.0 mm.

Allopurinol 300 mg is White to off white, round, biconvex with beveled edge uncoated tablet with inscription "AX" on one side and plain on the other side having approximate diameter of 11.2 mm.

PVC-ALU blister containing 25, 28, 30, 50, 60, 90 and 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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

Manufacturer

Accord Healthcare Polska Sp.z o.o.,
ul. Lutomska 50,95-200 Pabianice, Poland

LABORATORI FUNDACIÓ DAU

C/ C, 12-14 Pol. Ind. Zona Franca,
Barcelona, 08040, Spain

Accord Healthcare Single Member,
64th KM Athens Lamia National Highway,
Schimatari, Viotia, 32009, Greece

This medicine is authorised in the Member States of the European Economic Area under the following names:

Name of the Member State	Name of the medicine
Germany	Allopurinol Accord 100 mg, 300 mg Tabletten
Austria	Allopurinol Accord 100 mg, 300 mg tabletten
Denmark	Allopurinol Accord 100 mg, 300 mg tabletter
Estonia	Allopurinol Accord
Finland	Allopurinol Accord
Lithuania	Allopurinol Accord 100 mg, 300 mg tabletės
Latvia	Allopurinol Accord 100 mg, 300 mg tabletes
Netherlands	Allopurinol Accord 100 mg, 300 mg tabletten
Sweden	Allopurinol Accord 100 mg, 300 mg tabletter
Ireland	Allopurinol 100 mg, 300 mg tablet
Czech Republic	Allospes
Poland	Allospes
Cyprus	Allopurinol Accord 100 mg tablet
Italy	Allopurinolo Accord

Spain	Allopurinol Accord 100 mg, 300 mg comprimidos
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This leaflet was last revised in December 2024.