

Package leaflet: information for the user
Allopurinol Accord 100 mg tablets
Allopurinol Accord 300 mg tablets
Allopurinol

Read the entire leaflet carefully before you start using this medicine because it contains important

information for you. Keep this leaflet. You may need to read it again.

- Do you have any questions? Contact your doctor or pharmacist.
- Do not pass this medicine on to others, as it has been prescribed only for you. It may harm them, even if their symptoms are the same as yours.
- Do you experience any side effects listed in section 4? Or do you experience a side effect not mentioned in this leaflet?
- Do you experience any of the side effects listed in section 4? Or do you experience a side effect not mentioned in this leaflet? your doctor or doctor or pharmacist.

Contents of this leaflet

1. What is Allopurinol Accord and what is this medicine used for?
2. When should you not use this medicine or be extra careful with it?
3. How do you use this medicine?
4. Possible side effects
5. How do you store this medicine?
6. Contents of the package and other information

1. What is Allopurinol Accord and what is this medicine used for?

Allopurinol Accord contains the active substance allopurinol. Allopurinol belongs to a group of medicines called enzyme inhibitors. These medicines help control the rate at which certain chemical changes occur in the body.

This medicine is used for conditions where the body produces too much uric acid, such as: gout (painful inflammation caused by crystallized uric acid in a joint), certain kidney diseases or kidney stones; cancer and some metabolic diseases, which lead to a buildup of too much uric acid.

2. When should you not use this medicine or be extra careful with it?

When should you not use this medicine?

- You are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6 of this leaflet. If you are not sure, talk to your doctor before using this medicine use.

When should you be extra careful with this medicine?

Contact your doctor or pharmacist before using this medicine:

- if you have or have had liver or kidney disease
- if you are taking medicines (diuretics and/or an ACE inhibitor) for heart conditions or high blood pressure

- if you have a sudden attack of gout (painful inflammation caused by crystallized uric acid in a joint)
- if you are of Han Chinese, Thai, or Korean descent.
- if you thyroid problems have

Be extra careful with this medicine

If you have kidney stones. The kidney stones will become smaller and there is a small chance that they will enter and block your urinary tubes

Rashes have been reported with the use of allopurinol. These rashes are often accompanied by sores in the mouth, throat, nose, and genitals, and with conjunctivitis (red and swollen eyes). These severe forms of rashes are often preceded by flu-like symptoms, such as fever, headache, body aches. The rash can worsen to widespread blistering and peeling of the skin. These severe skin reactions may occur more frequently in people of Han Chinese, Thai, or Korean descent. Chronic kidney disease may further increase the risk in these patients. If you develop a rash or these skin reactions, stop using allopurinol and contact your doctor immediately. If you have cancer or the

Lesch-Nyhan syndrome (a metabolic disorder), the amount of amount to dilute your urine. drink to dilute your urine.

Children and adolescents up to 18 years

The use of this medicine in children is very rare, except in certain forms of cancer (especially leukemia) and some metabolic diseases such as the Lesch-Nyhan syndrome.

Are you taking any other medicines?

Are you taking any other medicines besides Allopurinol Accord or have you recently done so or are you perhaps going to do so soon? Tell that then your doctor or pharmacist.

medicines that suppress the natural defenses (immunosuppressants), e.g. 6-mercaptopurine, azathioprine and ciclosporin

adenine arabinoside (vidarabine), used for the treatment of herpes or chickenpox

other medicines for the treatment of gout, such as probenecid

aspirin (or similar medicines, called salicylates)

chlorpropamide, used for the treatment of diabetes

medicines that thin the blood (anticoagulants), such as warfarin

medicines used for the treatment of a seizure (uncontrollable body jerks, often as part of an epileptic seizure), phenytoin

theophylline, used for breathing problems

medicines against certain bacterial infections (antibiotics) (ampicillin or amoxicillin)

medicines used for the treatment of cancer

didanosine, used for the treatment of the infectious disease HIV (Human immunodeficiency virus)

medicines for heart problems or high blood pressure, such as ACE inhibitors (certain group of blood pressure-lowering medicines) or water pills (diuretics)

Aluminum hydroxide (used to neutralize stomach acid), because this can reduce the effect of allopurinol. There must be an interval of at least 3 hours between the administration of these medicines. interval of at least 3 hours.

When administering Allopurinol Accord and cytostatics (e.g., cyclophosphamide, doxorubicin, bleomycin, procarbazine, alkyl halides), blood dyscrasias (a blood disorder) occur more frequently than when these active substances are administered alone.

Therefore it is necessary to regularly examine the blood . . .

When 6-mercaptopurine or azathioprine is given concurrently with [allopurine 5 product name], the dose of 6-mercaptopurine or azathioprine must be reduced because these substances then remain longer the dose of 6-mercaptopurine or azathioprine must be reduced because those substances then remain longer work. That could increase the risk of serious problems with your blood. In such a situation, 3 your doctor will closely monitor your blood during the treatment. Seek medical help immediately if you notice that you have an unexplained bruise, bleeding, fever, or a sore throat heave

Pregnancy, breastfeeding, and fertility

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor or pharmacist before using this medicine.

Allopurinol passes into human breast milk. This medicine is not recommended during breastfeeding.

Driving and using machines

This medicine can make some people drowsy or give them less control over their movements. You must not drive or use machines until you know how this medicine affects you.

Allopurinol Accord contains lactose

This medicine contains lactose (a type of sugar). If your doctor has told you that you cannot tolerate certain sugars, contact your doctor before using this medicine.

3. How to use this medicine?

Always use this medicine exactly as your doctor has told you. Are you unsure about the correct usage? Then contact your doctor.

The amount of this medicine that people need to take can vary greatly. Your doctor will decide which dose of this medicine is suitable for you.

Your doctor usually starts with a low dose of allopurinol (e.g., 100 mg/day) to reduce the chance of possible side effects. Your dose will be increased if necessary.

The usual starting dose is 100 to 300 mg per day, which can be taken as a single dose after a meal. The dosage can be increased to 900 mg per day, depending on how severe your condition is.

If you use a daily dose of more than 300 mg, your doctor may tell you to take that dose in smaller amounts, spread throughout the day to reduce the risk of side effects in your gastrointestinal tract.

If you are elderly or if your liver or kidneys do not work well, your doctor may prescribe you a lower dose, or you may need to wait longer between doses. If you receive dialysis two or three times a week, your doctor may prescribe you a dose of 300 or 400 mg, which you should take immediately after dialysis. Use in children and adolescents up to 18 years

Children and adolescents up to 15 years 10-20 mg/kg body weight/day up to a maximum of 400 mg per day divided over 3 administrations. This medicine is rarely used in children, with day divided into 3 administrations. This medication is rarely used in children, with exception of certain types of malignant conditions (especially leukemia) and certain metabolic diseases, for example Lesch-Nyhan-syndrome.

Method of administration

This medicine should be taken orally.

Take the tablets with a glass of water to make them easier to swallow.

Take your tablets after meals to reduce the risk of side effects such as nausea and vomiting.

Have you used too much of this medicine?

If you take too many tablets or if someone else accidentally takes your medicine, inform your doctor immediately or go to the nearest hospital. Take the medicine packaging with you. Signs of an overdose may include: nausea, vomiting, diarrhea, and dizziness.

Have you forgotten to take this medicine?

If you have forgotten to take your medicine, take it as soon as you remember. However, if it is almost time for the next dose, skip the missed dose. Do not take a double dose to make up for a missed dose.

If you stop using this medicine

Do not stop using this medicine unless your doctor tells you to.

Do you have any other questions about using this medicine? Then contact your doctor or pharmacist.

4. Possible side effects

Like any medicine, this medicine can cause side effects. Not everyone experiences them.

Hypersensitivity

Sometimes (occur in less than 1 in 100 users)

Contact your doctor immediately if you have any of the following symptoms:

any skin changes, such as peeling skin, sores or painful lips and mouth

or in very rare cases sudden wheezing, pounding heartbeat or pressure on the chest, sudden collapse ('collapse')

Rarely (occur in less than 1 in 1000 users)

fever and chills, headache, muscle pain (flu-like symptoms) and you generally feel not feeling well

severe hypersensitivity reactions with fever, rash, joint pain, blood abnormalities and in tests that examine liver function (these may be signs of a hypersensitivity reaction involving multiple organs).

Your lips, eyes, mouth, nose, or genitals are bleeding.

any change in your skin, for example: sores in the mouth, throat, nose, genitals and inflammation of the conjunctiva causing itching, tearing, or redness (conjunctivitis), blisters or peeling over the entire body.

Very rarely (occur in less than 1 in 10,000 users)

severe allergic reaction that can cause swelling of the face or throat

severe, potentially life-threatening allergic reaction.

These symptoms may mean you are allergic to this medicine. Do not take any more tablets unless your doctor has told you to do so.

Other side effects

Common (occur in less than 1 in 10 users):

rash

increased amount thyroid-stimulating hormone (the hormone that ensures that the thyroid gland produces thyroid hormones) in the blood.

Sometimes (occur in less than 1 in 100 users)

nausea or vomiting (emesis);

abnormal liver values

diarrhea

Rarely (occur in less than 1 in 1,000 users)

liver problems, such as hepatitis.

Very rarely (occur in less than 1 in 10,000 users)

fever

blood in the urine (hematuria)

high cholesterol levels in your blood (hyperlipidemia)

you generally feel unwell or weak

weakness, numbness, unsteady on your feet, unable to move your muscles

(paralysis) or loss of consciousness

headache, dizziness, drowsiness or vision problems

pain in the chest (angina), high blood pressure or slow heart rate

your body retains fluid, leading to swelling (edema), especially in the ankles

diabetes (diabetes). Your doctor will want to measure the amount of sugar in your blood to determine if this is the case.

sometimes this medicine can affect your blood, causing you to bruise more easily than usual, or causing you to have a sore throat or other signs of an infection. These symptoms usually occur in people with liver or kidney problems. Contact your doctor as soon as possible if your

- medicine can affect your lymph nodes
- infertility
- infertility in men, erectile dysfunction
- enlargement of the breasts, in men and in women
- changes in your stool
- food and drink taste different than usual
- the clouding of the eye lens (cataract)
- hair loss or hair discoloration
- dejection (depression)
- problems with controlling muscle movements (ataxia)
- perception of tingling, itching, or tingling sensations without cause (paresthesia)

Not known (cannot be determined from the available data)

Aseptic meningitis (inflammation of the brain or spinal cord membranes): symptoms include Other a stiff neck, headache, nausea, fever, or reduced consciousness. Seek immediate medical assistance if these symptoms occur ..

Lichenoid skin rash (itchy red-purple skin rash and/or thread-like white-gray stripes on mucous membranes)

Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to side effects not listed in this leaflet. You can also report side effects via the Dutch Side Effects Center Lareb, website: www.lareb.nl. By reporting side effects, you help us obtain more information about the safety of this medicine.

5. How to store this medicine?

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date. You can find it on the box and the blister pack after EXP. It includes a month and a year. The last day of that month is the expiry date.

Store below 30 oC.

Do not flush medications down the sink or toilet and do not throw them in the trash. Ask your Pharmacist what to do with medications you no longer use. Proper disposal ensures they are destroyed responsibly and do not enter the environment. If you dispose of medications properly, they are destroyed responsibly and do not enter the environment.

6. Contents of the package and other information

What substances are in this medicine?

The active substance in this medicine is allopurinol.

Allopurinol Accord 100 mg tablets: Each tablet contains 100 mg of allopurinol.
Allopurinol Accord 300 mg tablets: Each tablet contains 300 mg of allopurinol.

The other substances in this medicine are:

Lactose monohydrate, crospovidone type B, maize starch, povidone K30 and magnesium stearate

What does Allopurinol Accord what does it look like and what is in a package?

Allopurinol Accord 100 mg tablets are white to off-white, round, biconvex tablets without film coating with a diameter of approximately 8.0 mm, with the imprint 'AW' on the one side and no imprint on the other side.

Allopurinol Accord 300 mg tablets are white to off-white, round, biconvex tablets without film coating with bevelled edges, with a diameter of approximately 11.2 mm and with the imprint 'AX' on one side and no imprint on the other side.

PVC-Alu blister pack with 25, 28, 30, 50, 60, 90, and 100 tablets.

Not all mentioned pack sizes are marketed.

Marketing authorization holder and manufacturer

Accord Healthcare B.V.

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Registered under

Allopurinol Accord 100 mg tablets RVG 121996

Allopurinol Accord 300 mg tablets RVG 121997

This medicine is registered in member states of the European Economic Area under the following names:

Name of the member state: Name of the medicine
Austria: Allopurinol Accord 100 mg, 300 mg tablets
Denmark: Allopurinol Accord 100 mg, 300 mg tablets
Estonia: Allopurinol Accord
Finland: Allopurinol Accord
Germany
: Allopurinol Accord 100 mg, 300 mg Tablets
Lithuania
Lithuania : Allopurinol Accord 100 mg, 300 mg tablets
Latvia: Allopurinol Accord 100 mg, 300 mg tablets
Netherlands: Allopurinol Accord 100 mg, 300 mg tablets
Sweden: Allopurinol Accord 100 mg, 300 mg tablets
Ireland: Allopurinol 100 mg, 300 mg tablet
Czech Republic: Allospes
Poland: Allospes
Cyprus: Allopurinol Accord 100 mg tablet
Italy: Allopurinol Accord
Spain : Allopurinol Accord 100 mg, 300 mg tablets

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