

PACKAGE LEAFLET: INFORMATION FOR THE USER

ALOPURINOL BELUPO

100 mg and 200 mg tablets

ALOPURINOL

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 •

What is in this leaflet?

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1. WHAT ALOPURINOL BELUPO IS AND WHAT IT IS USED FOR

Alopurinol Belupo contains a medicine called allopurinol. It works by slowing down certain accelerated chemical reactions that take place in your body.

Allopurinol is used for:

- prevention of gout (disease where the body produces large amounts of uric acid). Uric acid builds up in your joints and tendons in the form of crystals that cause inflammatory reactions. Due to inflammation, the skin around certain joints becomes swollen, painful and sensitive to the slightest touch. Also, severe pain occurs and when moving the affected joints;
- prevention of other conditions that caused accumulation of uric acid in the body such as the formation of kidney stones and other renal disorders, disorders of the enzyme during the treatment of some cancers.

2. BEFORE YOU TAKE ALOPURINOL BELUPO

Warn your doctor if you are taking other medicines, have a chronic disease, a metabolic disorder, you are hypersensitive to medicines or you have had an allergic reaction to some of them.

Do not take ALOPURINOL BELUPO in case of

- if you are hypersensitive (allergic) to allopurinol or to any of the excipients, (see section 6).

Take special care with ALOPURINOL BELUPO in

- you have a liver or kidney disease. Your doctor may give you a lower dose or recommend taking your medicine at intervals longer than one day. Also you will be more carefully and more frequently controlled;
- you have a heart disease or high blood pressure;
- you have a current acute attack of gout, which appeared after starting treatment with Alopurinol Belupo tablets;
- you have a rare form of sugar lactose intolerance. Alopurinol Belupo tablets contain small amounts of lactose. Tell your doctor that you have intolerance to some sugars and be sure to consult with him/her before taking this medicine.

In patients using allopurinol there were observed serious and severe skin reactions (hypersensitivity syndrome, Stevens-Johnson syndrome, and toxic epidermal necrolysis). Often, the rash can include the appearance of sores in the mouth, throat, nose, genitals and eyes (conjunctivitis with red and swollen eyes). These serious skin reactions are often preceded by a condition similar to a cold (flu), followed by fever, headache, pains in the body. The rash may progress; it may cause blisters and peeling of the skin. These serious skin reactions were observed more frequently in patients with impaired liver and kidney function, and with the yellow race (Chinese, Thai). If you experience a rash or above mentioned symptoms, immediately stop taking the medicine allopurinol and contact your doctor.

Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines. The following medicines may affect the treatment with Alopurinol tablets:

- aspirin;
- theophylline (for asthma);
- antiepileptics such as phenytoin, carbamazepine (to treat epilepsy);
- antibiotics e.g., ampicillin / amoxicillin (to treat bacterial infections);
- didanosine (for the treatment of HIV viral infections);
- azathioprine, mercaptopurine, cyclophosphamide (for the treatment of malignant disease-cancer);
- immunosuppressants such as cyclosporine (a medicine that prevents transplant rejection (transplant)
- authority);
- antidiabetics e.g. chlorpropamide and tolpropamid (for treating diabetes);
- ACE inhibitors and diuretics, (for the treatment of high blood pressure and heart disease);
- coumarin anticoagulants type dicoumarol eg, phenprocoumon, warfarin (to prevent
- blood clotting);
- any other medicines for the treatment of gout.

Taking food and drink with ALOPURINOL BELUPO tablets

It is recommended taking Alopurinol Belupo tablets with food and a glass of water.

Pregnancy and breast-feeding

Before taking any medicine, consult your doctor or pharmacist.

Contact your doctor before taking the medicine Alopurinol Belupo Tablets if you are pregnant, planning to become pregnant or are breast-feeding a baby.

It is not recommended taking the medicine Alopurinol Belupo during pregnancy and lactation.

Driving and using machines

Alopurinol Belupo tablets can cause dizziness, impaired coordination and thus affect the ability to drive and use machines. Do not operate a motor vehicle and do not operate machinery until you know how the medicine affects you.

Other warnings

In case of intolerance to some sugars, contact your doctor before taking this medicine, as it contains lactose.

3. HOW TO TAKE ALOPURINOL BELUPO

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

Swallow the tablets with a glass of water. Take it with food or immediately after meals.

Adults

The usual starting dose is 100 mg of allopurinol per day and can be increased only in special cases.

The following dosing scheme is recommended:

- 100 to 200 mg daily in mild cases,
- 300 to 600 mg daily in moderately severe conditions,
- 700 to 900 mg in severe condition.

If dosage per body weight is necessary, a dose of 2-10 mg / kg per day is recommended.

Children under 15 years: 10-20 mg / kg per day to a maximum of 400 mg per day. The use of allopurinol in children is rare, except in the case of malignant diseases (in particular leukemia) and certain enzyme disorders such as Lesch-Nyhan syndrome.

Elderly: due to lack of data, should use the lowest dose that provides the necessary reduction of urate concentration. Particular attention should be paid to dosing in case of renal failure (see Dosage in renal failure and Warnings and Precautions).

Chronic renal failure

In severe renal diseases, dose lower than 100 mg a day or a single dose of 100 mg a day is advised for an extended period of 24 hours. If you need dialysis two or three times a week, dosage of 300-400 mg of allopurinol, after each dialysis should be considered.

Liver disease

In patients with liver disease reduced dose of allopurinol should be used. During the early stages of therapy periodic biochemical control of liver function is recommended.

Treatment of condition with Uric Acid Nephrolithiasis (neoplasm, Lesch-Nyhan syndrome)

The dose of allopurinol should be at the lower limit of the recommended dosage regimen. In case that the formation of stone or other pathological conditions endangered kidney function, should adhere to the advice given in the part of dosing in renal disease. These procedures can reduce the risk of complicating of the clinical picture by deposition of xanthine and / or oxypurinol.

If you take more ALOPURINOL BELUPO than you should

Contact your doctor. If possible, bring a tablet, this instruction or packaging with you to show the doctor what you have taken.

If you forget to take ALOPURINOL Belupo chewable tablets

Do not take a double dose to make up for the forgotten tablet.

If you forget to take your medicine, take the missed dose the next day at the appointed time, and be sure to tell your doctor about it.

If you stop taking ALOPURINOL BELUPO

You should not suddenly stop taking the medicine without consulting your doctor.

Talk to your doctor or pharmacist if you have any additional questions.

4. POSSIBLE SIDE EFFECTS

Like all medicines, ALOPURINOL BELUPO can cause side effects, although not everybody gets them.

The following undesirable effects may occur when using allopurinol tablets:

Allergic reactions (affects less than 1 in 10,000 patients)

In the case of an allergic reaction, stop taking the medicine Alopurinol Belupo tablets and contact your doctor.

Symptoms include:

- skin rash, skin peeling, the occurrence of ulcers or wounds on the lips and in the mouth;
- rarely may occur whistling/flickering or heaviness in the chest and collapse (fainting).

Do not continue taking the tablets unless your doctor tells you otherwise.

If you encounter any of the following side effects immediately stop taking the tablets and contact your doctor as soon as possible:

Rare (affects less than 1 per 1,000 patients taking the medicine)

- joint pain or aching swelling in the groin, armpit or neck;
- yellowing of the skin and whites of the eyes (jaundice);
- problems with your liver or kidneys;
- nausea or presence of disease (vomiting), sometimes with traces of blood;
- changes in the skin in the form of sores in the mouth, throat, nose, genitals and eyes (conjunctivitis, red and swollen eyes), blistering and peeling of the skin;
- fever and chills, headache, muscle aches (influenza like state) and a feeling of general weakness;
- bleeding from the lips, eyes, mouth, nose or genitals;
- severe hypersensitivity reactions, which include fever, skin rash, joint pain and disorders of laboratory blood tests of liver function (it can be a sign of hypersensitivity that affects multiple organs).

Very rare (affects less than 1 in 10,000 patients taking the medicine)

- easier bruising than usual, easier development of sore throat or other signs of infection.
- Immediately consult your doctor. Occasionally, allopurinol may affect the blood or lymph system. This effect occurs mainly in patients with liver or kidney disease.
- fever;
- blood in the urine (haematuria);
- elevated cholesterol levels in the blood (hyperlipidemia);
- a general feeling of weakness;
- weakness, numbness, unsteady on your feet, inability to move the muscles (paralysis) or loss of consciousness;
- headache, dizziness, drowsiness and visual disturbances;
- chest pain, high blood pressure and weak pulse;
- sterility in men or full impotence (erectile impotence);
- breast enlargement in men and women;
- changes in normal bowel emptying;
- taste disturbance;

- cataract;
- hair loss or loss of hair color (gray hair);
- seizures;
- depression;
- accumulation of fluid leading to edema (swelling), especially in the joints;
- feeling of thirst, fatigue and weight loss; This can be signs of diabetes (diabetes mellitus). In this case, your doctor may want to check the level of sugar in your blood.

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.

5. HOW TO STORE ALOPURINOL BELUPO

Keep out of the reach and sight of children.

Do not use ALOPURINOL BELUPO after the expiry date which is stated on the label.

Shelf life: 2 years.

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What ALOPURINOL BELUPO contains

The active substance is allopurinol.

One Alopurinol Belupo tablet contains 100 mg of allopurinol.

One Alopurinol Belupo tablet contains 200 mg of allopurinol.

Other ingredients: lactose monohydrate; povidone; starch, corn; magnesium stearate.

What ALOPURINOL BELUPO looks like and contents of the pack

Alopurinol 100 mg tablet is white, round, flat with beveled edges and without mark on both sides.

Alopurinol 100 mg tablets:

Immediate packing: white polypropylene vials on which there is a safety lock consisting of white polypropylene caps, stoppers of natural polyethylene color and the security layer (ring) of LD polyethylene and polypropylene inner screw.

Outer packaging: folding cardboard box in which there are the white polypropylene bottles with 100 tablets and patient information leaflet.

Alopurinol 200 mg tablet is white, round, biconvex, without mark on both sides.

Alopurinol 200 mg tablets:

Immediate packing: PVC // Al blister, which contains 10 tablets.

Outer packaging: folding cardboard box that contains 5 blisters of 10 tablets and patient information leaflet.

Regime of dispensing

The medicine is issued on doctor's prescription.

Manufacturer

BELUPO, DD,

Ulica Danica 5, Koprivnica, Croatia