

Allopurinol 100 mg, 300 mg, tablets

what is allopurinol and what is it used for?

- 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.
- Allopurinol tablets are used for the long-term (chronic) prevention (prevention) of gout and can be used for other conditions related to too much uric acid in the body, such as kidney stones and other kidney diseases.

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 other substances in this medicine. You can find these substances in section 6.

When should you be extra careful with this medicine?

Contact your doctor or pharmacist before using this medicine: • If you are of Han Chinese, Thai, or Korean descent. • If you have liver and kidney problems. Your doctor may give you a lower dose or ask you to take it less frequently than once a day. He/she will also monitor you very closely.

If you have heart conditions or high blood pressure and if you are taking diuretics (medications to help you urinate) and/or medications called ACE inhibitors (a group of blood pressure-lowering medications).

- If you are currently experiencing a gout attack (sudden onset of pain caused by uric acid deposits in the joints and tendons).
- If you have thyroid problems.

If you are unsure if any of the above situations apply to you, please contact your doctor or pharmacist before taking allopurinol.

Be extra careful with this medicine: • Serious skin rash (hypersensitivity syndrome, Stevens-Johnson syndrome, toxic epidermal necrolysis) has been reported with the use of allopurinol. This rash can be recognized by sores in the mouth, throat, nose, and genitals, and inflammation of the eye mucous membrane that may itch, tear, or become red (conjunctivitis). These severe skin rashes often start with flu-like symptoms such as fever, headache, and body pain. The rash can worsen to widespread blistering and skin detachment.

These severe skin reactions may occur more frequently in people of Han Chinese, Thai, or Korean descent. Long-term (chronic) kidney disease can increase the risk in these patients even further.

If you experience skin rash or these skin reactions, stop using allopurinol immediately and contact your doctor.

- If you have kidney stones, they may become smaller and can enter your urinary tract.
- If you have cancer or Lesch-Nyhan syndrome (a metabolic disorder), the amount of uric acid in your urine may be higher than normal. To prevent this, you need to drink enough to dilute your urine.

Children: The use of this medicine in children is almost never mentioned, except for certain types of cancer (especially leukemia) and some enzyme disorders such as Lesch-Nyhan syndrome.

Are you using any other medicines?

If you are using other medicines in addition to Allopurinol Aurobindo, if you have used them recently, or if you may use other medicines in the near future, please inform your doctor or pharmacist. This is especially important for: • 6-mercaptopurine (used in the treatment of blood cancer). • Azathioprine, cyclosporine (used to suppress the immune system). NB: side effects of cyclosporine may occur more frequently. • Vidarabine (used in the treatment of herpes (a virus)). NB: vidarabine side effects may occur more frequently. Be extra careful if these side effects occur. • Salicylates (used to reduce pain, fever, or inflammation, such as aspirin). • Probenecid (used to treat gout (a often very painful metabolic disorder caused by the deposition of uric acid in the joints and tendons)). • Chlorpropamide (used to treat diabetes). Lowering the dose of chlorpropamide is sometimes necessary, especially if your kidneys are not functioning normally. • Warfarin, fenprocoumon, acenocoumarol (used to thin the blood). Your doctor will monitor your blood clotting values more frequently and, if necessary, lower the dose of these drugs. • Phenytoin (used in the treatment of epilepsy).

Theophylline (used to treat asthma and other respiratory diseases).

Your doctor will measure the amount of theophylline in your blood, especially at the beginning of treatment with allopurinol, or after adjusting the dose.

- Ampicillin or amoxicillin (used to treat bacterial infections).

When possible, patients should receive other antibiotics because allergic reactions occur more frequently.

- Medicines to treat aggressive tumors, such as:
 - cyclophosphamide
 - doxorubicin
 - bleomycin
 - procarbazine
 - mechlorethamine.

Your doctor will regularly check your blood.

- Didanosine (used in the treatment of HIV infection; the virus that can cause AIDS).
- Blood pressure-lowering agents (ACE inhibitors, such as captopril) or diuretics (used to treat high blood pressure).

The risk of skin reactions may be increased, especially if your kidneys have not been working properly for a long time.

If aluminum hydroxide is taken at the same time, allopurinol may have a weakened effect. There should be a minimum interval of 3 hours between taking these medicines.

When allopurinol is administered with cytostatics (such as cyclophosphamide, doxorubicin, bleomycin, procarbazine, alkyl halides), blood dyscrasias (a blood disorder) occur more frequently than when these active substances are administered alone (without other substances).

Therefore, regular blood tests should be performed.

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including over-the-counter medicines and herbal remedies. This medicine may affect the action of some medicines. Also, some other medicines may affect the action of this medicine.

Pregnancy and breastfeeding

Are you pregnant, think you might be pregnant, want to become pregnant, or are you breastfeeding? Then contact your doctor or pharmacist before using this medicine. Allopurinol is excreted in human breast milk. Allopurinol is not recommended during breastfeeding. You should not use this medicine if you are pregnant or breastfeeding unless your doctor has recommended it to you.

Driving and using machines

This medicine can cause dizziness, drowsiness, and problems with controlling your movements (coordination problems). If you experience any of these, you must NOT drive, operate machinery or participate in hazardous activities.

Allopurinol contains lactose

If your doctor has told you that you are intolerant to certain sugars (you have galactose intolerance, Lapp lactase deficiency, or glucose-galactose malabsorption), you must not use this medicine.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, which means it is essentially 'sodium-free'.

How to use this medicine?

Always use this medicine exactly as your doctor or pharmacist has told you. If you are unsure about the correct usage, please contact your doctor or pharmacist.

You should take your tablets after meals with a glass of water. As long as you are using this medicine, you should drink sufficient fluids (2-3 liters per day).

Your doctor usually starts 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 recommended dosage is: • Adults (including older people): Starting dose: 100-300 mg/day.

When you start your treatment, your doctor may also prescribe an anti-inflammatory drug or colchicine for a month or more to prevent attacks of gouty arthritis (a frequently painful metabolic disease caused by the deposition of uric acid in the joints and tendons).

Your allopurinol dose may be adjusted depending on the severity of your condition. The maintenance dose is: • Mild conditions, 100-200 mg/day • Moderately severe conditions, 300-600 mg/day • Severe conditions, 700-900 mg/day. Your doctor may also adjust your dose if you have impaired kidney and liver function, especially if you are older.

If the daily dosage is higher than 300 mg/day and you experience gastrointestinal side effects such as nausea or vomiting (see section 4), your doctor may prescribe allopurinol in divided doses to reduce these side effects.

If you have a severe kidney condition: • You may be asked to take less than 100 mg per day. • Or you may be asked to take 100 mg at longer intervals than 1 day.

If you are dialyzed two to three times a week (removal of waste products from the blood by filtration), your doctor may prescribe a dose of 300 or 400 mg. This should be taken immediately after your dialysis.

• Children (up to 15 years old): 100-400 mg/day

Treatment can be started with an anti-inflammatory drug or colchicine, and the dose can be adjusted if your kidneys or liver function poorly. The dose can be divided to reduce gastrointestinal side effects as mentioned for adults above.

Have you used too much of this medicine?

If you (or someone else) take too many tablets at once or if you think a child has swallowed tablets, immediately contact the emergency department of the nearest hospital or your doctor. An overdose will likely cause symptoms such as nausea, vomiting, diarrhea, or dizziness.

Take this leaflet, the remaining tablets, and the packaging to the hospital or doctor so they know which tablets have been taken.

Did you forget to use this medicine?

If you forget to take a tablet, take it as soon as you remember unless it is almost time for the next dose. Do NOT take a double dose to make up for a missed one. Take the remaining doses at the right time.

If you stop using this medicine

You should continue taking these tablets for as long as your doctor tells you to. DO NOT stop taking your medicine without consulting your doctor first.

If you have any other questions about using this medicine, please contact your doctor or pharmacist.

Possible Side Effects

Like all medicines, this medicine can have side effects, although not everyone gets them.

- Stop using this medicine and contact your doctor immediately if you notice the following symptoms:

An unexpected skin reaction (possibly in combination with fever, swollen glands, joint pain, unusual blistering or bleeding, kidney problems, or a sudden onset of seizures (uncontrollable body shocks, often as part of an epileptic seizure)).

Skin rash is the most common side effect of allopurinol (occurs in less than 1 in 10 users).

Rarely (occurs in less than 1 in 1000 users): • Fever and chills, headache, painful muscles (flu-like symptoms), and a general feeling of unwellness (malaise). • Any skin change, such as ulcers in the mouth, throat, nose, and genitals, and inflammation of the eye mucosa that causes itching, tearing, or redness (conjunctivitis), widespread blistering, or skin detachment. • Severe allergic reaction with fever, skin rash, joint pain, and abnormalities in blood and abnormal liver function tests (these may be signs of a hypersensitivity reaction involving multiple organs).

Allergic reactions (occur in less than 1 in 10,000 users): If you have an allergic reaction, stop taking allopurinol and contact a doctor immediately. Symptoms may include: • Skin rash, scaly skin, boils, or painful lips and mouth. • Swelling of the face, hands, lips, tongue, or throat. • Difficulty swallowing or breathing. • Very rarely, symptoms may include sudden wheezing, restlessness or tightness in the chest, and fainting.

Do not take any more tablets unless your doctor tells you to. If you notice any of the following symptoms while using this medicine, stop taking your tablets and contact your doctor immediately:

Other side effects: Commonly (occur in less than 1 in 10 users):• Skin rash.

Increased levels of thyroid-stimulating hormone (the hormone that stimulates the thyroid to produce thyroid hormones) in the blood. The following side effects have been reported sometimes (occurs in less than 1 in 100 users): • Nausea, vomiting (very rarely, blood may be present in vomit), and diarrhea. • Increased results from tests that measure how well your liver is functioning.

The following side effects are rare (occurs in less than 1 in 1000 users): • Joint pain or painful swelling in the groin, armpits, or neck. • Jaundice (yellowing of the skin and whites of the eyes). • Can affect the function of your liver or kidneys. • Formation of stones in the urinary tract, symptoms may include blood in urine and pain in the abdomen, flank, or groin.

How to store this medicine?

- Keep out of sight and reach of children.
- There are no special storage conditions for this medicine.