

Package leaflet: Information for the user

Allopurinol Orion 100 mg tablets

Allopurinol Orion 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 Orion is and what it is used for
2. What you need to know before you take Allopurinol Orion
3. How to take Allopurinol Orion
4. Possible side effects
5. How to store Allopurinol Orion
6. Contents of the pack and other information

1. What Allopurinol Orion is and what it is used for

Allopurinol belongs to a group of medicines called enzyme inhibitors, which act to control the speed at which special chemical changes occur in the body.

Allopurinol Orion tablets are used for the long-term, preventative treatment of gout and may be used in other conditions associated with an excess of uric acid in the body, including kidney stones and other types of kidney disease.

Children aged under 15 years: Only Allopurinol Orion 100 mg tablets may be used for children aged under 15 years. The 300 mg tablets contain a colouring agent (Sunset Yellow FCF aluminium lake, E110) that is not recommended for use in children and adolescents.

2. What you need to know before you take Allopurinol Orion

Do not take Allopurinol Orion:

- if you are allergic to allopurinol or any of the other ingredients of this medicine (listed in section 6)
- if you are currently having an attack of gout or have just had an attack of gout.

Warnings and precautions

Talk to your doctor or pharmacist before taking Allopurinol Orion tablets if you

- have problems with your liver and kidneys. Your doctor may give you a lower dose or ask you to take it less often than each day. Your doctor will also monitor you more closely.
- have heart problems or high blood pressure
- have thyroid problems
- are currently having an attack of gout.

Serious skin rashes (hypersensitivity syndrome, Stevens–Johnson syndrome, toxic epidermal necrolysis) have been reported with the use of 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 are not sure if any of the following applies to you, talk to your doctor or pharmacist before taking allopurinol.

Other medicines and Allopurinol Orion tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without prescription.

Tell your doctor before you start to take this medicine if you are taking:

- 6-mercaptopurine (used to treat blood cancer)
- azathioprine, ciclosporin (used to suppress the immune system). Please note, cyclosporine side effects may occur more frequently.
- vidarabine (used in the treatment of herpes). Please note, vidarabine side effects can occur more frequently. Take special care if these occur.
- salicylates (used to reduce pain, fever or inflammation, e.g. Aspirin)
- probenecid (used to treat gout)
- chlorpropamide (used to treat diabetes). Chlorpropamide dose reduction may be necessary, particularly in patients with reduced kidney function.
- warfarin, phenprocoumon, acenocoumarol (used to thin the blood). Your doctor will monitor your blood clotting values more frequently and if necessary, reduce the dose of these medicines.
- furosemide, thiazides or other diuretics (used to treat high blood pressure)
- phenytoin (used to treat epilepsy)
- theophylline (used to treat asthma and other breathing diseases). Your doctor will measure theophylline blood levels, particularly when treatment with Allopurinol begins, or following any dosage changes.
- ampicillin or amoxicillin (used to treat bacterial infections). Patients should receive other antibiotics where possible, as allergic reactions are more likely to occur with these two antibiotics.

The co-administration of 6-mercaptopurine or azathioprine with allopurinol should be avoided. When 6-mercaptopurine or azathioprine is given concurrently with Allopurinol Orion, 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.

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.

Your doctor will monitor your blood counts frequently if you are taking:

- didanosine (used to treat HIV infection)
- captopril (used to treat high blood pressure).

The risk of skin reactions can be raised, especially if your kidney function is chronically reduced.

Pregnancy, breast-feeding and fertility

If you are pregnant, planning to become pregnant or are breast-feeding, 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 Orion tablets can cause dizziness, drowsiness, and can affect your coordination. If you are affected, **do not** drive, operate machinery or participate in dangerous activities.

Allopurinol Orion contains lactose

Allopurinol Orion 100 mg tablet contains 48.2 mg and 300 mg tablet contains 145.9 mg of lactose (as monohydrate). If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicine.

Allopurinol Orion 300 mg tablets contain colouring agent Sunset Yellow FCF aluminium lake (E110)

Allopurinol Orion 300 mg tablet contains 2.6 mg of colouring agent Sunset Yellow FCF aluminium lake (E110) which may cause allergic reactions. The 300 mg tablets are not recommended for use in children aged under 15 years.

Other excipients

This medicine contains less than 1 mmol (23 mg) sodium per tablet, that is to say essentially 'sodium-free'.

3. How to take Allopurinol Orion

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The tablet can be divided into equal doses. The tablets should be swallowed with a drink of water. You should take your tablets after a meal. Please ensure sufficient fluid intake when taking this medicine, discuss with your doctor what could be an appropriate amount of fluid intake for you.

The recommended doses are:

Adults, adolescents (15–18 years), elderly

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.

Starting dose: 100–300 mg/day.

When you start your treatment, your doctor may also prescribe an anti-inflammatory medicine or colchicine for a month or more, to prevent attacks of gouty arthritis.

Your dose of allopurinol may be adjusted depending on the severity of the 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 dose may also be altered by your doctor if you have reduced kidney and liver function, particularly if you are elderly.

If the daily dose exceeds 300 mg/day and you are suffering from gastrointestinal side effects such as nausea or vomiting (see section 4), your doctor may prescribe allopurinol in divided doses to reduce these effects.

If you have a serious kidney problem

- you may be asked to take less than 100 mg each day or
- you may be asked to take 100 mg at longer intervals than one day.

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.

Only Allopurinol 100 mg tablets:

Children aged under 15 years

100–400 mg/day.

Treatment may be started together with an anti-inflammatory medicine or colchicine, and the dose adjusted if you have reduced kidney and liver function, or divided to reduce gastrointestinal side effects, as for Adults above.

If you take more Allopurinol Orion than you should

If you (or someone else) swallow a lot of the tablets all together or if you think a child has swallowed any of the tablets, contact your nearest hospital casualty department or your doctor immediately.

An overdose is likely to cause effects including nausea, vomiting, diarrhoea, or dizziness.

Please take this leaflet, any remaining tablets, and the container with you to the hospital or doctor so that they know which tablets were consumed.

If you forget to take Allopurinol Orion

If you forget to take a tablet, take one as soon as you remember, unless it is nearly time to take the next one. **Do not** take a double dose to make up for a forgotten dose. Take the remaining doses at the correct time.

If you stop taking Allopurinol Orion

You should continue to take these tablets for as long as your doctor tells you to. **Do not** stop taking your medicine without talking to your doctor first.

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.

Stop taking Allopurinol Orion and contact a doctor immediately if you experience

- an unexpected skin reaction (possibly in association with fever, swollen glands, joint pain, unusual blistering or bleeding, kidney problems or a sudden onset of fits).

Common (may affect up to 1 in 10 people):

- skin rashes
- increased level of thyroid stimulating hormone in the blood.

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

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

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

Allergic reactions

If you have an allergic reaction, stop taking allopurinol and see a doctor straight away. The signs may include:

- skin rash, flaking skin, boils or sore lips and mouth
- swelling of the face, hands, lips, tongue or throat
- difficulty swallowing or breathing
- very rarely signs may include sudden wheeziness, fluttering or tightness of the chest and collapse.

Do not take any more tablets unless your doctor tells you to do so.

If you experience any of the following while you are taking Allopurinol Orion, stop taking your tablets and tell your doctor as soon as possible:

Uncommon (may affect up to 1 in 100 people):

- nausea, vomiting (very rarely, blood may be present) and diarrhoea
- symptoms of allergic reactions, including itchy rash
- increase in results of liver function tests.

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

- joint pain or painful swelling in the groin, armpits or neck
- jaundice (yellowing of the skin and whites of the eyes)
- may affect your liver or kidney function
- formation of stones in the urinary tract; symptoms may include blood in the urine and pain in the abdomen, flank or groin.

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

- fever
- blood in the urine
- a change in your normal bowel habit, or unusual foul-smelling bowel movements
- high fat levels in the blood
- a general feeling of being unwell
- weakness, numbness, unsteadiness on feet, inability to move muscles (paralysis) or loss of consciousness, pins and needles
- convulsions, fits or depression
- headache, dizziness, drowsiness or disturbance of vision
- chest pain, high blood pressure or a slow pulse
- retention of fluid leading to swelling (oedema), particularly of the ankles
- male infertility or inability to get or maintain an erection, or ejaculation during sleep (“wet dreams”)
- enlargement of the breasts, in men as well as women
- a change in taste perception, inflammation in the mouth
- cataracts (clouding of the lens of the eye) and other problems with sight
- boils (small tender red lumps on the skin)
- hair loss or discolouration
- feeling thirsty, tired and losing weight (these may be symptoms of diabetes); your doctor may wish to measure the level of sugar in your blood to decide if this is happening
- muscle pain
- swollen glands, usually goes away once treatment with allopurinol ends
- serious allergic reaction which causes swelling of the face or throat
- serious potentially life-threatening allergic reaction.

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).

You may occasionally feel sick, but this can usually be avoided by taking allopurinol after meals. Tell your doctor if this problem persists.

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 occurred in people with liver or kidney problems. Tell your doctor as soon as possible.

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 [the national reporting system](#) listed in [Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Allopurinol Orion

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 carton and blister. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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 Orion contains

- The active substance is allopurinol. Each 100 mg tablet contains 100 mg of allopurinol. Each 300 mg tablet contains 300 mg of allopurinol.
- The other ingredients are lactose monohydrate, maize starch, povidone, sodium starch glycolate, and stearic acid. Allopurinol Orion 300 mg tablets also contain colouring agent Sunset Yellow FCF al. lake (E110).

What Allopurinol Orion looks like and contents of the pack

Allopurinol Orion 100 mg tablets are white to off-white-coloured, round, biconvex uncoated tablets with “AL” & “100” separated by breakline on one side and plain on the other side.

Allopurinol Orion 300 mg tablets are peach-coloured, round, biconvex uncoated tablets with “AL” & “300” separated by breakline on one side and plain on the other side.

Allopurinol Orion 100 mg tablets are available in packs of 50 and 100.
Allopurinol Orion 300 mg tablets are available in packs of 30 and 100.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Orion Corporation
Orionintie 1
FI-02200 Espoo
Finland

Manufacturer

Orion Corporation Orion Pharma
Orionintie 1
FI-02200 Espoo
Finland

Orion Corporation Orion Pharma
Joensuunkatu 7
FI-24100 Salo
Finland

For any information about this medicine, please contact the local representative of the Marketing
Authorisation Holder:
[To be completed nationally]

This leaflet was last revised in 27-Feb-2025