

PACKAGE LEAFLET

Package leaflet: Information for the patient

Allopurinol Viatris 100 mg tablets

Allopurinol Viatris 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 Viatris is and what it is used for
2. What you need to know before you take Allopurinol Viatris
3. How to take Allopurinol Viatris
4. Possible side effects
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1. What Allopurinol Viatris is and what it is used for

Allopurinol Viatris contains a medicine called allopurinol. It works by slowing down the speed of certain chemical reactions in your body to lower the level of uric acid in your blood and urine and prevents the formation of uric acid crystals.

Allopurinol Viatris is used in conditions where your body produces too much uric acid. These may include gout or kidney stones or some other types of kidney problems or when you are having treatment for cancer. In gout the uric acid builds up in your joints and tendons as crystals that may cause inflammation, swelling and pain.

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

Do not take Allopurinol Viatris:

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Allopurinol Viatris:

- if you have problems with your liver and kidneys
- if you have ongoing attacks of gout
- if you are of Han Chinese, Thai or Korean origin
- if you have thyroid problems

Take special care Allopurinol Viatris:

- 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 flu-like symptoms such as fever, headache, body ache. 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 help prevent this it's important to drink sufficiently to dilute your urine.
- If you have kidney stones, the stones may become smaller and enter the urinary tract, which could cause problems.

Children

Allopurinol Viatris should not be given to children under 6 years of age because it is not known if it is safe.

Other medicines and Allopurinol Viatris

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

It is especially important to tell your doctor if you are taking any of the medicines listed below. Your doctor may need to reduce the dose of your medicine and/or monitor you more carefully because of the increased risk of side effects when Allopurinol Viatris is taken at the same time as:

- mercaptopurine (used to treat blood cancer)
- azathioprine, ciclosporin (used to suppress the immune system):
the co-administration of 6-mercaptopurine or azathioprine with allopurinol should be avoided. When 6-mercaptopurine or azathioprine is given concurrently with Allopurinol Viatris, 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.
- vidarabine (used in the treatment of herpes)
- salicylates (used to reduce pain, fever or inflammation, e.g. acetylsalicylic acid)
- probenecid (used to treat gout)
- chlorpropamide (used to treat diabetes)
- warfarin, phenprocoumon, acenocoumarol (used to thin the blood)
- phenytoin (used to treat epilepsy)
- theophylline (used to treat asthma and other lung diseases)
- ampicillin or amoxicillin (used to treat bacterial infections)
- cytostatics (used to treat aggressive tumours):
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.
- didanosine (used to treat HIV infection)
- diuretics (water tablets) or ACE-inhibitors (certain medicines to treat blood pressure).

If aluminium hydroxide (used to neutralise the acid in the stomach) is taken concomitantly, allopurinol may have an attenuated effect. There should be an interval of at least 3 hours between taking both medicines.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

You should not take this medicine if you are pregnant unless advised by your doctor.

Allopurinol is excreted in the human breast milk. Allopurinol during breastfeeding is not recommended.

Driving and using machines

Allopruinol Viatris can cause dizziness, drowsiness, and can affect your coordination. If you are affected, **do not** drive, operate machinery or participate in dangerous activities.

Allopurinol Viatris contains lactose and sodium

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. This medicine also contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Allopurinol Viatris

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 score line is not intended for breaking the tablet. The tablets should be swallowed with a drink of water. You should take your tablets after a meal to reduce the risk of side effects such as nausea (feeling sick) and vomiting.
- If the daily dose exceeds 300 mg a day and you are suffering from gastrointestinal side effects such as nausea (feeling sick) or vomiting (see section 4), your doctor may prescribe divided doses to reduce these effects.
- Your dose may be altered by your doctor if you have reduced kidney and liver function.
- 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 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 recommended doses are:

Adults and adolescents ages 15-18 years old

Starting dose: 100 mg a day

Your dose of allopurinol may be adjusted depending on the severity of the condition:

- mild conditions: 100 to 200 mg a day.
- moderately severe conditions: 300 to 600 mg a day.
- severe conditions: 700 to 900 mg a day.

If you have kidney problems:

- 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 (this is because allopurinol is removed during dialysis).

Allopurinol Viatris 100 mg tablets only

Children and adolescents between 6 and 15 years weighing at least 15 kg

Recommended dose is 10 to 20 mg per kg body weight daily, divided into 3 doses.

Maximum daily dose is 400 mg.

Do not give this medicine to children under 6 years of age because it is not known if it is safe.

Allopurinol Viatris is rarely given to children, except with certain types of cancer (e.g. leukaemia) and some other conditions.

If you take more Allopurinol Viatris 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 side effects including nausea, vomiting, diarrhoea, or dizziness.

Please take this package 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 Viatris

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 Viatris

You should continue to take these tablets for as long as 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.

Stop taking Allopurinol Viatris and contact a doctor immediately if you experience:

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

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

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

- signs of serious allergic reaction which can be life threatening such as swelling of the face, lips, tongue or throat which may cause difficulty in breathing and swallowing, flaking or itchy skin, boils or sore lips and mouth, sudden wheeziness, fluttering or tightness of the chest, itchy and collapse. Do not take any more tablets unless your doctor tells you to do so.
- vomiting blood.

Contact your doctor as soon as possible if you experience any of the following side effects:

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

- inflammation of the liver (hepatitis) with symptoms that may include yellowing of the skin and whites of the eyes, poor appetite, vomiting, abdominal pain, diarrhoea.

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

- reduction in certain type of white blood cells resulting in frequent infections, such as sore throat or high temperature (fever) or ulcers in your mouth or throat; reduction in red blood cells or platelets (seen in blood tests) resulting in signs such as paleness, tiredness and bleeding or bruising more easily than normal. These effects usually occur in people with liver or kidney problems.

Not known (cannot be estimated from 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.

Other possible side effects:

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

- skin rashes
- increased level of thyroid stimulating hormone in the blood which may be seen in blood tests

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

- nausea (feeling sick), vomiting and diarrhoea
- symptoms of allergic reactions, including itchy rash
- increased liver function values.
- diarrhoea

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

- may affect your liver or kidney function
- formation of stones in the urinary tract with symptoms that 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):

- joint pain or painful swelling in the groin, armpits or neck
- fever
- blood in the urine
- a change in your normal bowel habit, or unusual foul-smelling bowel movements
- excessive fat in bowel motions causing diarrhoea
- 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, inability to get or maintain an erection, breast enlargement in men
- a change in taste perception, sore mouth, mouth ulcers and cold sores
- 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, joint pain
- swollen glands, usually goes away once treatment with allopurinol ends
- presence of urea in blood (uraemia) which may be seen in blood tests.

Not Known (cannot be estimated from available data):

- 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.

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 [\[To be completed nationally\]](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Allopurinol Viatris

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 after 'EXP'. The expiry date refers to the last day of that month.

This medicine 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 Viatris contains

- The active substance is allopurinol.
- Each tablet contains 100 mg allopurinol.
Each tablet contains 300 mg allopurinol.
- The other ingredients are lactose monohydrate (see section 2 ‘Allopurinol Viatris contains lactose’), maize starch, povidone, sodium starch glycolate and stearic acid.

What Allopurinol Viatris looks like and contents of the pack

Allopurinol Viatris 100 mg tablets are white to off-white coloured, round, biconvex uncoated with ‘AL’ and ‘100’ separated by a score line on one side and plain on the other side.

Allopurinol Viatris 300 mg tablets are white to off-white coloured, round, biconvex uncoated with ‘AL’ and ‘300’ separated by a score line on one side and plain on the other side.

Allopurinol Viatris 100 mg tablet is available in blister packs of 20, 50, 60, 90 and 100 tablets

Allopurinol Viatris 300 mg tablet is available in blister packs of 30, 60, 90 and 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

[To be completed nationally]

Manufacturer

Mylan Hungary Kft., H-2900, Komárom, Mylan útca.1, Hungary

This medicinal product is authorised in the Member States of the EEA under the following names:

Italy	Allopurinolo Mylan
Norway	Allopurinol Viatris
Portugal	Alopurinol Mylan
Sweden	Allopurinol Viatris

This leaflet was last revised in

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