

Package leaflet: Information for the patient.

ZYLORIC 100 mg and 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, nurse 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, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

Zyloric contains the active substance allopurinol. This medicine belongs to a group of medicines called enzyme inhibitors, which control the speed at which certain chemical changes occur in your body.

Zyloric Tablets are used to treat conditions where too much uric acid is produced by your body such as: gout; certain types of kidney disease and kidney stones; cancer and some enzyme disorders which lead to the build-up of too much uric acid.

2. What you need to know before you take Zyloric

Do not take Zyloric if:

- you ever had an allergy (rash, itching, shortness of breath) to Zyloric, allopurinol or any of the other tablet ingredients listed in section 6 of this leaflet

If you are not sure, check with your doctor first before taking the medicine.

Warnings and precautions

Talk to your doctor before taking Zyloric about/ if:

- you are suffering, or have you suffered, from liver or kidney disease
- you are taking medicines (diuretics and/or a medicine called ACE inhibitors) for heart disease or high blood pressure
- you are experiencing an acute attack of gout
- you are of Han Chinese, African or Indian origin
- you have thyroid problems.

Take special care with Zyloric:

- if you have kidney stones. The kidney stones will become smaller and may have a small chance of entering and blocking your urinary tract
- skin rashes have been reported in patients taking 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 have cancer or Lesch-Nyhan syndrome the amount of uric acid may increase in your urine. To prevent this, you need to assure to drink sufficiently to dilute your urine.

Children

Use in children is rarely indicated, except in some types of cancer (especially leukaemia) and certain enzyme disorders such as Lesch-Nyhan syndrome.

Other medicines and Zyloric

It is important to let your doctor know if you are taking any of the following drugs (please check with your doctor if you are not sure):

- medicines used to reduce your immune response (immunosuppressants) e.g. 6-mercaptopurine, azathioprine and cyclosporin
- adenine arabinoside (vidarabine), used to treat herpes or chickenpox
- other medicines to treat gout, such as probenecid
- aspirin (or related drugs called salicylates)
- chlorpropamide, used to treat diabetes
- drugs which thin the blood (anticoagulants), such as warfarin
- medicines used for fits (epilepsy), phenytoin
- theophylline, used for breathing problems
- antibiotics (ampicillin or amoxicillin)
- drugs used for the treatment of cancer
- didanosine, used to treat HIV infection
- medicines for heart problems or high blood pressure such as ACE inhibitors or water tablets (diuretics).

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.

Pregnancy and breast-feeding

If you are pregnant, breast-feeding, think you might be pregnant or are planning to have a baby, 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

Zyloric tablets may make some people drowsy or have problems with their coordination. Do not drive or operate machinery until you know how it affects you.

Zyloric Tablets contain lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before you take Zyloric tablets.

3. How to take Zyloric

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure. The label on the pack will tell you how many tablets to take and how often to take them. If the label does not say or if you are not sure, ask your doctor or pharmacist.

The back of the Zyloric 300 mg tablet blister strip is marked with the days of the week to help check that you have taken a dose each day. Press your first tablet out through the foil marked with today's day - for example, if today is Tuesday, use one marked 'Tue'; move on to the 'Wed' tablet tomorrow, and so on. Follow the arrows and do not start another blister strip of tablets until the first is finished. You should then start a new blister strip, every two weeks, on the same day of the week that you started the first one.

The amount of Zyloric that people can take can be very different. Your doctor will decide on a dose of Zyloric that is right for you.

The usual starting dose is in the range 100 to 300 mg daily, which may be taken as a single dose, after a meal. The tablets should be taken with a glass of water to make swallowing easier. The dose may be increased up to 900 mg daily, depending on the severity of your condition.

Dosage higher than 300 mg should be given in divided doses not exceeding 300 mg at any one time.

If you are an older person or if you have reduced liver or kidney function, your doctor may prescribe a lower dose or to take it at longer intervals. 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.

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.

Use in children (under 15 years)

The usual dose is in the range 100-400 mg daily.

If you take more Zyloric than you should

If you take too many tablets or someone else takes your medicine by mistake, tell your doctor at once or go to the hospital straight away. Take the medicine pack with you. Signs of an overdose may include nausea, vomiting, diarrhoea and dizziness.

If you forget to take Zyloric

If you forget to take a dose, take another one as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose. Do not take a double dose to make up for the forgotten.

If you stop taking Zyloric

Do not stop taking your Zyloric Tablets unless your doctor tells you to.

If you have any further questions on the use of this medicine, ask your doctor, nurse or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Hypersensitivity

Uncommon (may affect less than 1 in 100 people)

Check with your doctor **immediately** if you experience any of the following:

- a reaction of any kind such as flaking skin, boils or sore lips and mouth
- or very rarely, sudden wheeziness, fluttering or tightness in the chest; collapse

Rare (may affect less than 1 in 1000 people)

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

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

- serious allergic reaction which causes swelling of the face or throat
- serious potentially life-threatening allergic reaction

THESE SYMPTOMS MAY MEAN THAT YOU ARE ALLERGIC TO ZYLORIC. Do **NOT** take any more tablets unless your doctor tells you to do so.

Other side effects

Common (may affect less than 1 in 10 people)

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

Uncommon (may affect less than 1 in 100 people)

- feeling sick (nausea) or being sick (vomiting)
- abnormal liver tests
- diarrhoea

Rare (may affect less than 1 in 1000 people)

- Liver problems such as liver inflammation.

Very rare (may affect less than less than 1 in 10.000 people)

- high temperature
- blood in your urine (haematuria)
- high levels of cholesterol in your blood (hyperlipidaemia)
- a general feeling of being unwell or feeling weak
- weakness, numbness, unsteadiness on your feet, feeling unable to move muscles (paralysis) or loss of consciousness
- headache, dizziness, drowsiness or disturbance of vision
- chest pain (angina), high blood pressure or a slow pulse
- retention of fluid leading to swelling (oedema) particularly of the ankles
- abnormal glucose metabolism (diabetes). Your doctor may wish to measure the level of sugar in your blood to help to decide if this is happening.
- occasionally Zyloric 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 occur in people with liver or kidney problems. Tell your doctor as soon as possible.
- Zyloric may affect the lymph nodes
- male infertility, impotence
- enlargement of the breasts, in men as well as women
- a change in your normal bowel habit
- change in taste perception
- cataracts
- hair loss or discolouration
- depression

- lack of voluntary coordination of muscle movements (ataxia)
- sensation of tingling, tickling, pricking or burning of skin (paraesthesia)

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.

If you experience any of these side effects, or if you notice any side effects not listed in this leaflet while you are taking Zyloric please tell your doctor or pharmacist at once:

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. You can also report side effects directly via:

Ireland

HPRRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie.

Malta

ADR Reporting

Website: www.medicinesauthority.gov.mt/adrportal.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Zyloric

Keep this medicine out of the reach and sight of children.

Do not store above 25°C.

Store your tablets in the original pack.

Do not take this medicine after the expiry date, which is stated on the blister and carton. The expiry date refers to the last date of the stated month on which the product can be used.

Return any unwanted tablets to your pharmacist. Do not throw away any medicines via waste water 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 Zyloric contains:

The active substance is allopurinol.

The other ingredients are: lactose monohydrate, maize starch, povidone and magnesium stearate.

What Zyloric looks like and contents of the pack

Zyloric 100 mg Tablets are white to off-white with the marking "Z1" and a single line scored on one side. Each tablet contains 100 mg of the active ingredient, allopurinol. Zyloric 100 mg Tablets come in blister strips of 28 or 100 tablets.

Zyloric 300 mg Tablets are white to off-white with the marking "Z3" and a single line scored on one side. Each tablet contains 300 mg of the active ingredient, allopurinol. Zyloric 300 mg Tablets come in blister strips of 28 tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorization Holder

Aspen Pharma Trading Limited, 3016 Lake Drive, Citywest Business Campus, Dublin 24, Ireland.

Manufacturer

Aspen Bad Oldesloe GmbH, Industriestrasse 32-36, 23843 Bad Oldesloe, Germany.

Medical Information Enquiries

For any Medical Information enquiries about this product, please contact:

Ireland

Tel: 00353 1 630 8400

Malta

Tel: 00356 21497982

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