

# Package Leaflet: Information for the User

## Zyloric® 100 mg and 300 mg tablets

### allopurinol

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it onto others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### In this leaflet:

- 1 What Zyloric is and what it is used for
- 2 Before you take Zyloric
- 3 How to take Zyloric
- 4 Possible side effects
- 5 How to store Zyloric
- 6 Further information

### 1 What Zyloric is and what it is used for

Zyloric tablets contain a medicine called allopurinol. It works by slowing down the speed of certain chemical reactions in your body. Zyloric is used:

- to prevent gout. This is a disease where your body produces too much of a substance called 'uric acid'. The uric acid builds up in your joints and tendons as crystals. These crystals cause an inflammatory reaction. The inflammation causes the skin around certain joints to become swollen, tender and sore when only slightly touched. You can also find you get severe pain when the joint is moved.
- to prevent other conditions where there is a build up of uric acid in the body. These include kidney stones and certain other types of kidney problem and when you are having treatment for cancer.

### 2 Before you take Zyloric

**Do not take Zyloric if:**

- you are allergic (hypersensitive) to allopurinol or any of the other ingredients of Zyloric (listed in Section 6).

Do not take Zyloric if the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Zyloric.

**Take special care with Zyloric**

Check with your doctor or pharmacist before taking your medicine if:

- you have problems with your liver or kidneys. Your doctor may give you a lower dose or ask you to take it less often than each day. They will also monitor you more closely
- You have heart problems or high blood pressure
- you are currently having an attack of gout
- you have been told by your doctor that you have an intolerance to lactose. Zyloric tablets contain a small amount of lactose. **If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.**

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 or Thai origin. 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 above applies to you, talk to your doctor or pharmacist before taking Zyloric.

**Taking other medicines**

Tell your doctor or pharmacist if you are taking any of the following:

- aspirin
- theophylline, used for breathing problems

- medicines used for fits (epilepsy)
- antibiotics
- didanosine, used to treat HIV infection
- medicines for cancer
- medicines used to reduce your immune response (immunosuppressants)
- medicines used to treat diabetes
- medicines for heart problems or high blood pressure such as 'ACE inhibitors' or water tablets (diuretics)
- medicines used to thin your blood (anticoagulants), such as warfarin
- any other medicine to treat gout.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription, including herbal medicines. This is because Zyloric can affect the way some medicines work. Also some other medicines can affect the way Zyloric works.

**Taking Zyloric with food and drink**

Take Zyloric with food and water.

**Pregnancy and breast-feeding**

Talk to your doctor before taking this medicine if you are pregnant, might become pregnant or are breast-feeding.

**Driving and using machines**

You may feel drowsy, giddy or have problems with your co-ordination. If this happens, do not drive or use any tools or machines.

### 3 How to take Zyloric

Always take Zyloric exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

**Taking this medicine**

- Swallow the tablet with a drink of water.
- Take with or just after food.

**Children (under 15 years)**

- The usual dose ranges from 100 to 400 mg each day.

**Adults (over 18 years)**

- The usual dose ranges from 100 to 900 mg each day. You will usually start on a dose of 100 to 300 mg each day.

**Elderly (over 65 years)**

- Your doctor will prescribe the lowest dose of Zyloric tablets that best controls your symptoms.

**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.

**If you take more Zyloric than you should**

If you take more Zyloric than you should, talk to a doctor or go to hospital straight away. Take the medicine pack with you.

**If you forget to take Zyloric**

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

**If you stop taking Zyloric**

Do not stop taking your Zyloric without talking to your doctor. If you have any further questions on the use of this product, ask your doctor or pharmacist.

Please turn  
over the page

#### 4 Possible side effects

Like all medicines, Zyloric can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

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

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

- skin rash, flaking skin, boils or sore lips and mouth
- very rarely signs may include sudden wheeziness, fluttering or tightness in 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, stop your tablets and tell your doctor as soon as possible:**

**Rare** (affects less than 1 in 1000 people)

- joint pain or painful swelling in your groin, armpits or neck
- yellowing of the skin and eyes (jaundice)
- liver or kidney problems
- feeling sick (nausea) or being sick (vomiting), occasionally with blood
- bleeding in the lips, eyes, mouth, nose or genitals
- 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** (affects less than 1 in 10,000 people)

- bruising more easily than usual, or you may develop a sore throat or other signs of an infection. Tell your doctor as soon as possible. Occasionally Zyloric tablets may affect your blood or lymph system. These effects usually occur in people with liver or kidney problems
- high temperature
- blood in your urine (haematuria)
- high levels of cholesterol in your blood (hyperlipidaemia)
- a general feeling of being unwell
- weakness, numbness, unsteadiness on your feet, feeling unable to move muscles (paralysis) or loss of consciousness
- headache, dizziness, drowsiness or disturbance of your vision
- chest pain, high blood pressure or a slow pulse
- male infertility or erectile dysfunction
- enlargement of the breasts, in men as well as women
- a change in your normal bowel habit
- a change in taste
- cataracts
- hair loss or discolouration
- fits (convulsions)
- depression
- build up of fluid leading to swelling (oedema) particularly of your ankles
- 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 check if this is happening.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### 5 How to store Zyloric

- Keep out of the reach and sight of children.
- Do not use Zyloric after the expiry date which is stated on the carton after 'EXP'. The expiry date refers to the last day of that month.
- Keep your tablets in the original packaging.
- Do not store above 25°C.
- Medicines should not be disposed of via wastewater or household waste.
- Return any unused or unwanted tablets to your pharmacist for disposal. Only keep them if your doctor tells you to. These measures will help to protect the environment.

#### 6 Further information

What Zyloric contains

- The active substance is allopurinol.
- The other ingredients are lactose, maize starch, povidone and magnesium stearate.

#### What Zyloric looks like and contents of the pack

Zyloric tablets contain 100 or 300 mg allopurinol. Each 100 mg tablet is white, round and marked with a score line, Z1.

Each 300 mg tablet is white, round and marked with a score line, Z3.

Zyloric 100 mg tablets come in 4 strips of 25 tablets.

Zyloric 300 mg tablets come in 2 strips of 14 tablets.

#### Marketing Authorisation Holder

Aspen Pharma Trading Limited  
12/13 Exchange Placel.F.S.C, Dublin 1, Ireland  
Service-Tel: +800 00404142

#### Manufacturer

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

Leaflet date: November 2012

Zyloric is a registered trademark of the Aspen

