

## **Package leaflet: Information for the patient**

**Alopur 100 mg Tablets**

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

### **1. What Alopur is and what it is used for**

Alopur 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.

Alopur Tablets are used to treat conditions where too much uric acid is produced in 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 Alopur**

#### **Do not take Alopur**

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

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

#### **Warnings and precautions**

Talk to your doctor before taking Alopur about/if:

- you are of Han Chinese, African or Indian origin
- 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 and you take diuretics and/or a medicine called ACE-inhibitors.
- you are currently having an attack of gout
- you have thyroid problems
- skin rashes (Hypersensitivity syndrome, Stevens-Johnson syndrome, toxic epidermal necrolysis) 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.
- in case you have kidney stones, the kidney stones will become smaller and may enter your urinary tract.

### **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 Alopur**

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

The following medicines can influence or be influenced by Alopur:

- acetylsalicylic acid
- theophylline, used for breathing problems
- medicines used for fits (epilepsy), phenytoin
- vidarabine, used to treat herpes or chickenpox
- antibiotics (ampicillin or amoxicillin)
- didanosine, used to treat HIV infection
- medicines used for cancer
- medicines used to reduce your immune response such as 6-mercaptopurine, azathioprine and cyclosporin (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.

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.

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 this medicine can affect the way some medicines work. Also some other medicines can affect the way this medicine works.

### **Pregnancy and breast-feeding**

Talk to your doctor before taking this medicine if you are pregnant, might become pregnant or are breast-feeding. Allopurinol is excreted in the human breast milk. Allopurinol during breast-feeding is not recommended.

### **Driving and using machines**

Alopur 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.

## **3. How to take Alopur**

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

### **Adults**

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

The recommended 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.

Dose 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.

### **Use in children (under 15 years)**

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

### **Tablet dividing instruction**

Divide the tablet as illustrated in this figure:



### **If you take more Alopur 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 Alopur**

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 and then go on as before. Do not take a double dose to make up for the forgotten dose.

### **If you stop taking Alopur**

Do not stop taking Alopur unless 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.

### **Hypersensitivity**

**Uncommon** (may affect up to 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
- very rarely, sudden wheeziness, fluttering or tightness in the chest; collapse.

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

- fever and chills, headache, aching muscles (flu-like symptoms) and generally feeling unwell
- serious hypersensitivity reactions involving fever, joint pain, abnormalities in blood
- bleeding in the lips, eyes, mouth, nose or genitals
- 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 ALOPUR. Do **NOT** take any more tablets unless your doctor tells you to do so.

### **Other side effects**

**Common**, may affect up to 1 in 10 people

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

**Uncommon**, may affect up to 1 in 100 people

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

**Rare**, may affect up to 1 in 1,000 people

- liver problems such as liver inflammation.

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

- occasionally Alopur 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.
- Alopur may affect the lymph nodes
- 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 your vision
- chest pain (angina), 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
- depression
- lack of voluntary coordination of muscle movements (ataxia)
- sensation of tingling, tickling, pricking or burning of skin (paraesthesia)
- build up of fluid leading to swelling (oedema) particularly of your ankles
- abnormal glucose metabolism (diabetes). Your doctor may wish to measure the level of sugar in your blood to check if this is happening.

**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 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.

### **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: HPRA Pharmacovigilance; website: [www.hpra.ie](http://www.hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine

## **5. How to store Alopur**

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 plastic-aluminium blister/tablet container and the carton after “EXP”. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

*For tablet containers:*

Shelf life after first opening of the tablet container: 6 months.

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 Alopur contains**

*For Alopur 100 mg*

- The active substance is allopurinol. Each tablet contains 100 mg of allopurinol.
- The other ingredients are microcrystalline cellulose, cellulose powdered, crospovidone, macrogol 4000, magnesium stearate, povidone K25, talc.

*For Alopur 300 mg*

- The active substance is allopurinol. Each tablet contains 300 mg of allopurinol.
- The other ingredients are microcrystalline cellulose, cellulose powdered, crospovidone, macrogol 4000, magnesium stearate, povidone K25, talc.

### **What Alopur looks like and contents of the pack**

*For Alopur 100 mg*

A white, round tablet rounded on the upper and lower side, with a single-sided score notch.

The tablet can be divided into equal doses.

The following pack sizes of the medicinal product are available:

- blisters with 1, 7, 10, 25, 28, 30, 50, 90 and 100 tablets
- tablet containers with 50, 100, 250, 500 and 1000 tablets.

Not all pack sizes and pack types may be marketed.

*For Alopur 300 mg*

A white to off-white, oblong tablet rounded on the upper and lower side, with a score notch on both

sides.

The tablet can be divided into equal doses.

The following pack sizes of the medicinal product are available:

- blisters with 1, 7, 10, 20, 28, 30, 50, 90, 100 and 105 tablets
- tablet containers with 20, 30, 50, 100, 105, 250, 500 and 1000 tablets.

Not all pack sizes and pack types may be marketed.

### **Marketing Authorisation Holder and Manufacturers**

#### **Marketing Authorisation Holder**

Rowex Ltd., Bantry, Co. Cork, Ireland.

#### **Manufacturers**

Salutas Pharma GmbH, Otto-von-Guericke Allee 1, 39179 Barleben, Germany.

LEK S.A., ul. Podlipie 16 C, 95 010 Strykow, Poland.

Lek Pharmaceuticals d.d., Verovškova 57, 1526 Ljubljana, Slovenia.

Lek Pharmaceuticals d.d., Trimlini 2D, Lendava, 9220, Slovenia.

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

Ireland Alopur 100 mg Tablets

Alopur 300 mg Tablets

**This leaflet was last revised in 12/2021.**