

Package Leaflet: Information for the user

Lotanos 12.5mg Film-coated Tablets

Losartan Potassium

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

1 What Lotanos is and what it is used for

Losartan belongs to a group of medicines known as angiotensin-II receptor antagonists.

Angiotensin-II is a substance produced in the body which binds to receptors in blood vessels, causing them to tighten. This results in an increase in blood pressure.

Losartan prevents the binding of angiotensin-II to these receptors, causing the blood vessels to relax which in turn lowers the blood pressure. Losartan slows the decrease of kidney function in patients with high blood pressure and type 2 diabetes.

Lotanos is used

- to treat patients with high blood pressure (hypertension) in adults and in children and adolescents 6 - 18 years of age
- to protect the kidney in hypertensive type 2 diabetic patients with laboratory evidence of impaired renal function and proteinuria ≥ 0.5 g per day (a condition in which urine contains an abnormal amount of protein).
- to treat patients with chronic heart failure when therapy with specific medicines called angiotensin-converting enzyme inhibitors (ACE inhibitors, medicine used to lower high blood pressure) is not considered suitable by your doctor. If your heart failure has been stabilised with an ACE inhibitor you should not be switched to losartan.
- in patients with high blood pressure and a thickening of the left ventricle, losartan has been shown to decrease the risk of stroke ('LIFE indication')

2 What you need to know before you take Lotanos

Do not take Lotanos if you:

- are **allergic** to losartan hydrochloride or any of the other ingredients of this medicine (listed in section 6)
- are more than 3 months pregnant (it is also better to avoid Lotanos in early pregnancy – see pregnancy section.)
- have severely **impaired liver** function

Warnings and precautions

Talk to your doctor or pharmacist before taking Lotanos if you:

- have **previously suffered from swelling of the face, lips, throat or tongue**
- have **primary hyperaldosteronism** (Conn's syndrome) a **tumour of the adrenal gland** associated with muscle weakness, excessive thirst and frequent urination
- are also **taking lithium** for mental health problems (see also 'Other medicines and Lotanos' below)
- take diuretics (**water pills**)
- are on a **salt-restricted diet**
- have had **severe vomiting** and/or **diarrhoea**
- have **impaired kidney or liver function**
- have **narrow arteries to your kidneys** (renal artery stenosis) or you have recently had a **kidney transplant**
- suffer from coronary heart disease (caused by a reduced blood flow in the blood vessels of the heart) or from cerebrovascular disease (caused by a reduced blood circulation in the brain)
- have **heart failure** with or without kidney impairment or concomitant severe life threatening cardiac arrhythmias
- have 'aortic or mitral valve stenosis' (**narrowing of the valves of the heart**) or hypertrophic cardiomyopathy' (a disease causing **thickening of heart muscle**)

Lotanos tablets **may be less effective in black people.**

You must tell your doctor if you think you are (or might become) pregnant. Lotanos is not recommended in early pregnancy, and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if used at that stage (see pregnancy section).

Other medicines and Lotanos

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

It is essential that you tell the doctor if you use the following medicines:

- lithium (a medicine for **treatment of mania or depression**)
- other blood pressure lowering medicines, as they may additionally reduce your blood pressure. Blood pressure may also be lowered by one of the following drugs/class of drugs: tricyclic antidepressants, antipsychotics, baclofene, amifostine
- medicines which retain potassium or may increase potassium levels (e.g. potassium supplements, potassium-containing salt substitutes or potassium-sparing medicines such as certain diuretics [amiloride, triamterene, spironolactone] or heparin
- non-steroidal anti-inflammatory drugs such as indomethacin, including cox-2-inhibitors and aspirin (medicines that reduce inflammation and can be used to help relieve pain) as they may reduce the blood pressure lowering effect of losartan

Ask your doctor if you are not sure what these medicines are.

Lotanos with food and drink

Lotanos may be taken with or without food.

Pregnancy and breastfeeding

Ask your doctor or pharmacist for advice before taking any medicine.

Pregnancy

You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking Lotanos before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Lotanos. Lotanos is not recommended in early pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.

Breastfeeding

Tell your doctor if you are breastfeeding or about to start breastfeeding. Lotanos is not recommended for mothers who are breastfeeding, and your doctor may choose another treatment for you if you wish to breastfeed, especially if your baby is newborn, or was born prematurely.

Driving and using machines

Dizziness and drowsiness has been reported by people taking Lotanos. If you experience this, do not drive or operate machinery.

Lotanos contains lactose monohydrate

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3 How to take Lotanos

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 decide on the appropriate dose of Lotanos, depending on your condition and whether you are taking other medicines. It is important to continue taking Lotanos for as long as your doctor prescribes it in order to maintain smooth control of your blood pressure.

Adult patients with high blood pressure

Treatment usually starts with 50mg losartan (one tablet Lotanos 50mg) once a day. The maximal blood pressure lowering effect should be reached 3-6 weeks after beginning treatment. In some patients the dose may later be increased to 100mg losartan (two tablets Lotanos 50mg) once daily. If you have the impression that the effect of losartan is too strong or too weak, please talk to your doctor or pharmacist.

Use in children and adolescents (6 to 18 years):

The recommended starting dose in patients who weigh between 20 and 50kg is 0.7mg of losartan per kg of bodyweight administered once a day (up to 25mg of Lotanos). The doctor may increase the dose if blood pressure is not controlled.

Adult patients with high blood pressure and type 2 diabetes

Treatment usually starts with 50 mg losartan (one tablet Lotanos 50 mg) once a day. The dose may later be increased to 100 mg losartan (two tablets Lotanos 50 mg) once daily depending on your blood pressure response.

Losartan tablets may be administered with other blood pressure lowering medicines (e.g. diuretics, calcium channel blockers, alpha- or beta-blockers, and centrally acting agents) as well as with insulin and other commonly used medicines that decrease the level of glucose in the blood (e.g. sulfonylureas, glitazones and glucosidase inhibitors).

Adult patients with heart failure

Treatment usually starts with 12.5mg losartan once a day. Generally, the dose should be increased weekly step-by-step (i.e. 12.5 mg daily during the first week, 25 mg daily during the second week, 50 mg daily during the third week, 100mg daily during the fourth week, 150mg daily during the fifth week) up to the maintenance dose as determined by your doctor. A maximum dose of 150mg losartan (for example, three tablets of Lotanos 50mg or one tablet each of Lotanos 100mg and Lotanos 50mg) once daily may be used. In the treatment of heart failure, losartan is usually combined with a diuretic (medicine that increases the amount of water that you pass out through your kidneys) and/or digitalis (medicines that helps to make the heart stronger and more efficient) and or a beta-blocker.

Dosage in special patient groups

The doctor may advise a lower dose especially when starting treatment in certain patients such as those treated with diuretic in high doses, in patients with liver impairment or in patients over the age of 75 years. The use of losartan is not recommended in patients with severe hepatic impairment (see section “Do not take Lotanos”).

Administration

The tablets should be swallowed with a glass of water. You should try to take your daily dose at about the same time each day. It is important that you continue to take Lotanos until your doctor tells you otherwise.

If you take more Lotanos than you should

If you accidentally take too many tablets, or a child swallows some, contact your doctor immediately. Symptoms of overdose are low blood pressure, increased heartbeat, possibly decreased heartbeat.

If you forget to take Lotanos

If you accidentally miss a daily dose, just take the next dose as normal. Do not take a double dose to make up for a forgotten tablet.

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

4. Possible side effects

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

If you experience the following, stop taking Lotanos and tell your doctor immediately or go to the casualty department of your nearest hospital:

A **severe allergic reaction** (rash, itching, swelling of the face, lips, mouth or throat that may cause difficulty in swallowing or breathing).

This is a serious but rare side effect, which affects more than 1 out of 10,000 patients but fewer than 1 out of 1,000 patients. You may need urgent medical attention or hospitalisation.

The following side effects have been reported:

Common: may affect more than 1 in 10 people

- dizziness, vertigo
- weakness, tiredness
- low blood pressure including feeling light-headed or weak when you stand up
- decreased blood sugar levels, increased potassium levels (which can cause an abnormal heart rhythm)
- reduced number of red blood cells (anaemia)
- increase in blood urea, serum creatinine and serum potassium in patients with heart failure
- kidney impairment, kidney failure

Uncommon: may affect up to 1 in 100 people

- sleepiness, sleep disorders
- headache
- feeling of increased heart rate (palpitations)
- angina (chest pain)
- stomach pain, constipation, vomiting, diarrhoea
- localised swelling
- shortness of breath
- nausea
- hives, itching, rash
- cough

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

- severe allergic reaction
- inflammation of blood vessels (vasculitis including Henoch-Schonlein purpura)
- numbness or tingling sensation (paraesthesia)
- fainting
- very rapid and irregular heartbeat (atrial fibrillation)
- brain attack (stroke)
- inflammation of the liver (hepatitis)
- elevated blood alanine aminotransferase (ALT) levels, usually resolved upon discontinuation of treatment

Not known: frequency cannot be estimated from the available data

- reduced number of blood platelets in blood, which may cause easy bruising or nasal bleeding (thrombocytopenia)
- impaired sense of taste
- ringing, buzzing, roaring or clicking in the ears
- migraine
- inflammation of the pancreas
- generally feeling unwell (malaise)
- liver function abnormalities
- sensitivity to light
- muscle pain, joint pain
- unexplained muscle pain with dark urine (rhabdomyolysis)
- impotence
- depression
- low sodium levels in the blood

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

Reports may be made by following the links to the online reporting option accessible from the IMB homepage, or by completing the downloadable report form also accessible from the IMB website, which may be completed manually and submitted to the IMB via freepost, to the following address:

FREEPOST

Pharmacovigilance Section
Irish Medicines Board
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.imb.ie
e-mail: imbpharmacovigilance@imb.ie

5 How to store Lotanos

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.

Do not store above 25°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer required. These measures will help protect the environment.

6 Contents of the pack and other information

What Lotanos contains

The **active substance** is losartan potassium.

Lotanos 12.5mg Film-coated Tablets contain 12.5mg losartan potassium.

The **other ingredients** are

Tablet core: microcrystalline cellulose, povidone, sodium starch glycolate (type A), colloidal anhydrous silica, magnesium stearate

Tablet film-coating: lactose monohydrate, hypromellose, titanium dioxide (E171), macrogol 4000, indigo carmine (E132) aluminium lake.

What Lotanos looks like and contents of the pack

Lotanos 12.5mg are blue, oval-shaped, film-coated tablets embossed with a '1' on one side.

Lotanos 12.5mg is packed in blister packs of 28 and 30 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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

Manufacturers

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

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

Lek S.A., Ul. Domaniewska 50C, 02-672 Warszawa, Poland

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