

PACKAGE LEAFLET

Package leaflet: Information for the patient

Losartan Viatris 12.5 mg film-coated tablets

Losartan Viatris 25 mg film-coated tablets

Losartan Viatris 50 mg film-coated tablets

Losartan Viatris 100 mg 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 Losartan Viatris is and what it is used for
2. What you need to know before you take Losartan Viatris
3. How to take Losartan Viatris
4. Possible side effects
5. How to store Losartan Viatris
6. Contents of the pack and other information.

1. What Losartan Viatris is and what it is used for

Losartan Viatris contains the active substance losartan, which 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 those receptors, causing 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.

Losartan Viatris 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, medicines 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 Losartan Viatris

Do not take Losartan Viatris:

- if you are allergic to losartan or any of the other ingredients of this medicine (listed in section 6).
- if your liver function is severely impaired.
- if you are more than 3 months pregnant (it is also better to avoid Losartan Viatris in early pregnancy – see pregnancy section).
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.

Warnings and precautions

Talk to your doctor or pharmacist before taking Losartan Viatris:

- if you have a history of angioedema (swelling of the face, lips, throat, and/or tongue) (see also section 4 ‘Possible side effects’).
- if you suffer from excessive vomiting or diarrhoea leading to an extreme loss of fluid and/or salt from your body.
- if you receive diuretics (medicines that increase the amount of water that you can pass out through your kidneys) or are under dietary salt restrictions leading to an extreme loss of fluid and salt in your body (see section 3 ‘Dosage in special patient groups’).
- if you are known to have narrowing or blockage of the blood vessels leading to your kidneys or if you have received a kidney transplant recently.
- if your liver function is impaired (see section 2 ‘Do not take Losartan Viatris’ and 3 ‘Dosage in special patient groups’).
- if you suffer from heart failure with or without renal impairment or concomitant severe life threatening cardiac arrhythmias. Special caution is necessary when you are treated with a β -blocker concomitantly.
- if you have problems with your heart valves or heart muscle.
- if you suffer from coronary heart disease (caused by a reduced blood flow in blood vessels of the heart) or from cerebrovascular disease (caused by a reduced blood circulation in the brain).
- if you suffer from primary hyperaldosteronism (a syndrome associated with increased secretion of the hormone aldosterone by the adrenal gland, caused by an abnormality within the gland).
- if you are taking any of the following medicines used to treat high blood pressure:
 - an ACE-inhibitor (for example enalapril, lisinopril, ramipril), in particular if you have diabetes-related kidney problems.
 - aliskiren.Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals.
See also information under the heading ‘Do not take Losartan Viatris’.
- if you are taking other medications that may increase serum potassium (see section 2 “Other medicines and Losartan Viatris”).

Talk to your doctor if you experience abdominal pain, nausea, vomiting or diarrhoea after taking Losartan Viatris. Your doctor will decide on further treatment. Do not stop taking Losartan Viatris on your own.

You must tell your doctor if you think you are (or might become) pregnant. Losartan 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).

Children and adolescents

Losartan has been studied in children. For more information, talk to your doctor.

Losartan is not recommended for use in children suffering from kidney or liver problems as limited data are available in these patient groups.

Losartan Viatris is not recommended for use in children under 6 years old, as it has not been shown to work in this age group.

Other medicines and Losartan Viatris

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

Take particular care if you are taking the following medicines while under the treatment with Losartan Viatris:

- 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, baclofen, amifostine.
- medicines which retain potassium or may increase potassium levels (e.g. potassium supplements or potassium-containing salt substitutes or potassium-sparing medicines such as certain diuretics [amiloride, triamterene, spironolactone] or other medicines that may increase serum potassium (e.g., heparin, trimethoprim-containing medicines), as the combination with Losartan Viatris is not advisable..
- non-steroidal anti-inflammatory drugs such as indometacin, including cox-2-inhibitors (medicines that reduce inflammation, and can be used to help relieve pain) as they may reduce the blood pressure lowering effect of losartan.

Your doctor may need to change your dose and/or to take other precautions:

- If you are taking an ACE-inhibitor or aliskiren (see also information under the headings “Do not take Losartan Viatris” and “Warnings and precautions”).

If your kidney function is impaired, the concomitant use of these medicines may lead to a worsening of the kidney function.

Lithium containing medicines should not be taken in combination with losartan without close supervision by your doctor. Special precautionary measures (e.g. blood tests) may be appropriate.

Losartan Viatris with food and drink

Losartan Viatris may be taken with or without food.

Grapefruit juice should be avoided while taking Losartan Viatris.

Pregnancy and breast-feeding

Pregnancy

You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking Losartan Viatris before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Losartan Viatris. Losartan Viatris 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.

Breast-feeding

Tell your doctor if you are breast-feeding or about to start breast-feeding. Losartan Viatris is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby is newborn, or was born prematurely.

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

Driving and using machines

No studies on the effects on the ability to drive and use machines have been performed. Losartan Viatris is unlikely to affect your ability to drive or use machines. However, as with many other medicines used to treat high blood pressure, losartan may cause dizziness or drowsiness in some people. If you experience dizziness or drowsiness, you should consult your doctor before attempting such activities.

Losartan Viatris contains lactose

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 Losartan 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.

Your doctor will decide on the appropriate dose of Losartan Viatris, depending on your condition and whether you are taking other medicines.

It is important to continue taking Losartan Viatris 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 50 mg losartan (one tablet Losartan Viatris 50 mg) 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 100 mg losartan (two tablets Losartan Viatris 50 mg) once daily.

If you have the impression that the effect of this medicine is too strong or too weak, please talk to your doctor or pharmacist.

Use in children and adolescents

Children below 6 years of age

Losartan Viatriis is not recommended for use in children under 6 years old, as it has not been shown to work in this age group.

Children aged 6 – 18 years old

The recommended starting dose in patients who weigh between 20 and 50 kg is 25 mg once daily (up to a maximum of 50 mg of losartan once daily. The doctor may increase the dose if blood pressure is not controlled.

Other form(s) of this medicine may be more suitable for children; ask your doctor or pharmacist.

Adult patients with high blood pressure and Type 2 diabetes

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

Losartan Viatriis 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 12.5 mg losartan (one tablet Losartan Viatriis 12.5 mg) 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, 100 mg daily during the fourth week, 150 mg daily during the fifth week) up to the maintenance dose as determined by your doctor. A maximum dose of 150 mg losartan (for example three tablets of Losartan Viatriis 50 mg) once daily may be used.

In the treatment of heart failure, losartan is usually combined with a diuretic (a medicine that increases the amount of water that you pass out through your kidneys) and/or digitalis (a medicine 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 diuretics 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 Losartan Viatriis').

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 Losartan Viatris until your doctor tells you otherwise.

If you take more Losartan Viatris 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 Losartan Viatris

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 dose.

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.

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

- rash, itching, swelling of the face, lips, mouth or throat that may cause difficulty in swallowing or breathing. These may be signs of a severe allergic reaction including angioedema. This is a serious but rare side effect, which may affect up to 1 in 1,000 people.
- unexplained muscle pain with dark (tea-coloured) urine. These may be signs of muscle problems (rhabdomyolysis). This is a serious side effect but its frequency is not known (cannot be estimated from the available data).

The following side effects have also been reported:

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

- dizziness
- low blood pressure (especially after excessive loss of water from the body within blood vessels e.g. in patients with severe heart failure or under treatment with high dose diuretics)
- dose-related orthostatic effects such as lowering of blood pressure appearing when rising from a lying or sitting position
- feeling or being weak
- fatigue
- reduced number of red blood cells (anaemia)
- too little sugar in the blood (hypoglycaemia,)
- too much potassium in the blood (hyperkalaemia)
- increase in blood urea
- increase in serum creatinine and serum potassium in patients with heart failure

- changes in kidney function, including kidney failure, which may cause changes in urination and pain in the lower back

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

- somnolence
- headache
- sleep disorders
- feeling of increased heart rate (palpitations)
- a feeling of tightness in the chest or severe chest pain (angina pectoris)
- shortness of breath (dyspnoea)
- cough
- abdominal pain
- obstipation
- diarrhoea
- nausea
- vomiting
- hives (urticaria)
- itching (pruritus)
- rash
- localised swelling (oedema)

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

- hypersensitivity
- inflammation of blood vessels (vasculitis including Henoch-Schonlein purpura)
- numbness or tingling sensation (paraesthesia)
- fainting (syncope)
- very rapid and irregular heartbeat (atrial fibrillation)
- brain attack (stroke)
- inflammation of the liver (hepatitis), which may cause yellowing of the skin and eyes (jaundice)
- elevated blood alanine aminotransferase (ALT) levels, usually resolved upon discontinuation of treatment
- a swelling in the gut presenting with symptoms like abdominal pain, nausea, vomiting and diarrhoea (intestinal angioedema)

Not known (frequency cannot be estimated from the available data):

- reduced number of thrombocytes
- ringing sound in ear (tinnitus)
- liver function abnormalities
- increased sensitivity to the sun (photosensitivity)
- migraine
- change in taste
- erectile dysfunction, impotence
- depression
- inflammation of the pancreas (pancreatitis), which causes severe pain in the abdomen
- muscle and joint pain
- low blood sodium levels (hyponatraemia), which would be seen in a blood test

- flu-like symptoms
- generally feeling unwell (malaise)
- back pain and urinary tract infection

Side effects in children are similar to those seen in adults.

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

Store in the original package.

Do not open the blister pack until you are ready to take the medicine.

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 Losartan Viatris contains

The active substance is losartan potassium.

Each tablet contains 12.5 mg, 25 mg, 50 mg or 100 mg of losartan potassium, equivalent to 11.44 mg, 22.88 mg, 45.76 mg or 91.52 mg of losartan.

The other ingredients are lactose monohydrate (see section 2 “Losartan Viatris contains lactose”), pre-gelatinised starch, microcrystalline cellulose, magnesium stearate. The coating includes hydroxypropylcellulose, hypromellose, titanium dioxide E171 and Brilliant Blue FCF Aluminium Lake E 133 (in 12.5mg tablets only).

What Losartan Viatris look like and contents of the pack

The film-coated tablets are round.

The 12.5 mg tablets are blue.

The 25 mg, 50 mg and 100mg tablets are white.

Losartan Viatris is available in blister packs of 7, 10, 14, 20, 21, 28, 28 (calendar pack), 30, 50x1, 56, 60, 98, 98 (calendar pack), 100, 210, and 280, 500* tablets.

HDPE Bottles of 100 & 250* tablets.

*Not all pack sizes may be marketed

Marketing Authorisation Holder and Manufacturer

<To be completed nationally>

This medicine is authorized in the Member States of the European Economic Area under the following names:

Member State	Invented name
Sweden	Losartan Viatris
Belgium	Losartan Viatris 12,5 mg, 25 mg, 50 mg & 100 mg filmomhulde tabletten
Italy	Losartan Mylan Generics

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