

Presartan Film-Coated Tablet 50mg, 100mg

Losartan Potassium 50mg, 100mg

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What Presartan is used for

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

Presartan 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 Potassium has been shown

to decrease the risk of stroke (“LIFE indication”).

How Presartan works

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.

Before you use Presartan

When you must not use it

Do not take Presartan:

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

Before you start to use it

Talk to your doctor or pharmacist or nurse before taking Losartan potassium. You must tell your doctor if you think you are (or might become) pregnant. Losartan potassium 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.

It is important to tell your doctor before taking Presartan:

- if you have had a history of angioedema (swelling of the face, lips, throat, and/or tongue),
- if you suffer from excessive vomiting or diarrhoea leading to an extreme loss of fluid and/or salt in your body,
- if you receive diuretics (medicines that increase the amount of water that you pass out through your kidneys) or are under dietary salt restriction leading to an extreme loss of fluid and salt in your body,
- 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,
- 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 the 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),

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- if you are taking any of the following medicines used to treat high blood pressure:

- an “ACE-inhibitor” (for example enalapril, lisinopril, ramipril, etc.), 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. If you are taking other medications that may increase serum potassium

Children and adolescents

Losartan potassium has been studied in children. For more information, talk to your doctor. Losartan potassium is not recommended for use in children suffering from kidney or liver problems, as limited data are available in these patient groups. Losartan potassium is not recommended for use in children under 6 years old, as it has not been shown to work in this age group.

Taking other medicines

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

Tell your doctor if you are taking potassium supplements, potassium-containing salt substitutes, potassium-sparing medicines such as certain diuretics (amiloride, triamteren, spironolactone), or other medicines that may increase serum potassium (e.g., heparin, trimethoprim-containing medicines), as the combination with Losartan potassium is not advisable. Take particular care

if you are taking the following medicines while under treatment with Presartan:

- 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,
- non-steroidal anti-inflammatory drugs such as indomethacin, 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.

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. Your doctor may need to change your dose and/or to take other precautions: If you are taking an ACE-inhibitor or aliskiren.

Presartan with food and drink and alcohol

Presartan may be taken with or without food. Grapefruit juice should be avoided while taking Presartan.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are

planning to have a baby, ask your doctor or pharmacist for advice before taking this 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 Losartan potassium before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Losartan potassium. Losartan potassium 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 potassium 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 a newborn, or born prematurely. Ask your doctor or pharmacist for advice before taking this medicine.

How to use Presartan

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 potassium, depending on your condition and whether you are taking other medicines. It is important to continue taking Losartan potassium

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for as long as your doctor prescribes it in order to maintain smooth control of your blood pressure. 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 Presartan until your doctor tells you otherwise.

How much to use

Adult patients with high blood pressure:

Treatment usually starts with 50 mg losartan (one tablet Presartan 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 potassium 50 mg) 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:

Children below 6 years of age Losartan potassium 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 to 18 years old The recommended starting dose in patients who weigh between 20 and 50 kg is 0.7 mg of losartan per kg of body weight administered once a day (up to 25 mg of Losartan potassium). 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 potassium 50 mg) once a day. The dose may later be increased to 100 mg losartan (two tablets Losartan potassium 50 mg or one tablet of Losartan potassium 100 mg) once daily depending on your blood pressure response.

Presartan 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 (half tablet Losartan potassium 25 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 physician. A maximum dose of 150 mg losartan (for example, three tablets of Losartan potassium 50 mg or one tablet each of Losartan potassium 100 mg and Losartan potassium 50 mg) 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 (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.

When to use it

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

How long to use it

Take this medicine for as long as your doctor tells you to.

If you forget to use it

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 medicine, ask your doctor or pharmacist.

If you use too much (overdose)

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

While you are using it

Things you must do

Take the medicine exactly as your doctor has told you.

Things you must not do

Do not exceed the recommended dosage, because this may put you at risk of low blood pressure, increased heartbeat, possibly decreased heartbeat. Do not take Losartan potassium without your doctor's advice, if you are pregnant.

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Things to be careful of

Contact your doctor if symptoms worsen or if a severe allergic reaction (rash, itching, swelling of the face, lips, mouth or throat that may cause difficulty in swallowing or breathing) occurs. Contact your doctor in case of overdose. Consult your doctor if any of the side effects get serious, or if you notice any side effects not listed in this leaflet. Presartan 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.

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: 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 hospitalization. The following side effects have been reported with Losartan potassium: 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, debility, fatigue, too little sugar in the blood (hypoglycaemia), too much potassium in the blood (hyperkalaemia), changes in kidney function including kidney failure, reduced number of red blood cells (anaemia), increase in blood urea,

serum creatinine and serum potassium in patients with heart failure.

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

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

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

- hypersensitivity, angioedema, inflammation of blood vessels (vasculitis including Henoch-Schönlein purpura), numbness or tingling sensation (paraesthesia), fainting (syncope), 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 thrombocytes, migraine, liver function abnormalities, muscle and joint pain, flu-like symptoms, back pain and urinary tract infection, increased sensitivity to the sun (photosensitivity), unexplained muscle pain with dark (tea-coloured) urine (rhabdomyolysis), impotence, inflammation of the pancreas (pancreatitis), low levels of sodium in the blood (hyponatraemia), depression, generally feeling unwell (malaise), ringing, buzzing, roaring, or clicking in the ears (tinnitus), disturbed taste (dysgeusia).

Side effects in children are similar to those seen in adults. You may report side effect or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumer → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and disposal of Presartan

Storage

Store below 30°C in a dry place, away

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

Disposal

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

Product Description

What it looks like?

Presartan-100: White to off white, almond shaped, biconvex, film coated tablets with '100' debossing on one side and 'BL' on the other side.

Presartan-50: White to off white, Oval, biconvex, film coated tablets with '50' debossing on one side and 'BL' on other side.

Ingredients

Active ingredient:

Presartan-50: Each film-coated tablet contains: Losartan Potassium USP 50 mg
Presartan-100: Each film-coated tablet contains: Losartan Potassium USP 100 mg

Inactive ingredients:

Maize starch, microcrystalline cellulose, colloidal silicone dioxide, sodium starch glycolate, purified talc, magnesium stearate, purified water, hydroxy propylmethyl cellulose-15 cps, titanium dioxide, purified talc, polyethylene glycol (PEG 6000)

MAL Number

Presartan-50: MAL14070003AZ
Presartan-100: MAL14070004AZ

Manufacturer

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Product Registration Holder

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