

LOSAGEN 25, LOSAGEN 50 and LOSAGEN 100

Losartan Potassium Tablets 25mg, Losartan Potassium Tablets 50mg and Losartan Potassium Tablets 100mg

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What *LOSAGEN* is used for

LOSAGEN is an angiotensin II receptor antagonist which lowers blood pressure.

If you have high blood pressure and a thickening of the left ventricle, the heart's main pumping chamber, your doctor has prescribed *LOSAGEN* to help lower the risk of cardiovascular events, such as stroke.

LOSAGEN also provides kidney protection by delaying the worsening of kidney disease in type 2 diabetic patients with protein in their urine (proteinuria) and reduce the need for dialysis or kidney transplantation. Kidney disease can be measured by testing the urine for protein.

How *LOSAGEN* works

LOSAGEN works by widening your blood vessels to make it easier for the heart to pump blood to all parts of your body. This helps to reduce high blood pressure. *LOSAGEN* also helps to lower the risk of cardiovascular events, such as stroke, in patients with high blood pressure and a thickening of the left ventricle of the heart. In addition to these blood pressure effects, *LOSAGEN* also helps protect your kidneys if you have type 2 diabetes with protein in the urine.

Before you take *LOSAGEN*

When you must not use it

- if you are allergic (hypersensitive) to losartan or to any of its other ingredients
- if you are more than 3 months pregnant (It is also better to avoid *LOSAGEN* in early pregnancy)

Before you start to take it

It is important to tell your doctor before taking *LOSAGEN*:

- if you have angioedema (swelling of the face, lips, throat, and/or tongue)
- if you suffer from excessive vomiting or diarrhea 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.

Taking other medicines

In general, *LOSAGEN* does not interact with food or other medicines you may be taking. You should, however, tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription or herbal medicines and natural products.

Take particular care if you are taking the following medicines while under treatment with *LOSAGEN*:

- other blood pressure lowering medicines as they may additionally reduce your blood pressure
- 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].
- non-steroidal anti-inflammatory medicines (medicines that reduce inflammation, relieve fever and pain) 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
- Lithium (a drug used to treat a certain kind of depression).

How to take *LOSAGEN*

How much to take

Always take *LOSAGEN* exactly as your doctor has

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

Adult patients with high blood pressure

Treatment usually starts with 50 mg *LOSAGEN* 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 *LOSAGEN* once daily. If you are taking high-dose diuretics a starting dose of 25mg once daily should be considered. No initial dosage adjustment is necessary for elderly patients or for patients with kidney impairment, including patients on dialysis. A lower dose should be considered for patients with a history of liver impairment.

High blood pressure patients with Left Ventricular Hypertrophy (thickening of the left ventricle, the heart's main pumping chamber)

The usual starting dose is 50 mg of *LOSAGEN* once daily. A low dose of hydrochlorothiazide should be added and/or the dose of *LOSAGEN* should be increased to 100 mg once daily.

Type 2 Diabetic Patients with protein in the urine and high blood pressure

The usual starting dose is 50 mg once daily. The dose may be increased to 100 mg taken once daily.

Use in children

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

Use in Black patients with high blood pressure and a thickening of the left ventricle

In a study in patients with high blood pressure and a thickening of the left chamber of the heart, *LOSAGEN* was shown to decrease the risk of stroke and heart attack, and help patients live longer.

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However, in this study, these benefits, when compared to another antihypertensive medicine called atenolol, did not apply to Black patients.

When to take it

You should try to take your daily dose at about the same time each day. Take your medicine preferably in the morning. Always take *LOSAGEN* exactly as your doctor has told you. *LOSAGEN* may be taken with or without food. The tablets should be swallowed with a glass of water.

How long to take it

It is important to continue taking *LOSAGEN* for as long as your doctor prescribes it in order to maintain smooth control of your blood pressure.

If you forget to take 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 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 taking it

Things you must do

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

Tell your doctor if you are breastfeeding or about to start breastfeeding. *LOSAGEN* 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 new born, or was born prematurely.

Things you must not do

You are advised not to drink alcohol whilst taking these tablets.

Things to be careful of

No studies on the effects on the ability to drive and use machines have been performed.

LOSAGEN 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, *LOSAGEN* can cause side effects, although not everybody gets them.

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

The most common drug-related side effects were asthenia/fatigue, dizziness, low blood pressure and increase level of potassium in the blood.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug

Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public → Reporting Medicinal Problems Side Effects / AEFI)"

Storage and Disposal of LOSAGEN

Storage

Keep out of the reach and sight of children. Store below 30°C

Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

What it looks like

LOSAGEN 25

White to off-white, film coated, Oval shaped tablets de-bossed with '1' on one side and '5' on the other side with score line

LOSAGEN 50

White to off-white, film coated oval shaped tablets de-bossed with '1' on one side and '6' on the other side with score line.

LOSAGEN 100

White to off-white, film -coated tear drop shaped tablets de-bossed with 'H' on one side and '145' on the other side.

Ingredients

Active ingredient:
Losartan potassium

Inactive ingredients:

Lactose monohydrate, Cellulose Microcrystalline, Low substituted hydroxyl propyl cellulose, Magnesium stearate, opadry white, Starch pregelatinised, Crospovidone and purified water.

MAL numbers:

Manufacturer

Unit V, Sy No 439,440,441,458, TSIC Formulation SEZ, Polepally village, Jedcharla Mandal, Mahaboob nagar-509301, Telangana, INDIA.

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Product Registration Holder

Unimed Sdn Bhd
No 53, Jalan Tembaga SD
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Date of revision

26/05/2017

Serial number:

NPRA(Rx/x)xxxxxx/xxxxx