

# LOSARTAS TABLETS

Losartan potassium tablets 25mg, 50mg & 100mg

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## What Losartas tablets are used for?

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

Losartan potassium is used:

1. To treat patient with high blood pressure (hypertension)
2. To protect the kidney in hypertensive type II diabetic patients with an elevated serum creatinine and proteinuria (urinary albumin to creatinine ratio  $\geq 300$  mg/g).
3. In patients with high blood pressure and a thickening of the heart wall, losartan potassium has been shown to decrease the risk of stroke.

Talk to your healthcare provider if you do not think that your condition is getting better with losartan potassium treatment.

## How Losartas tablets work?

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

## Before you use Losartas tablets.

*When you must not take it:*

Do not take losartan potassium tablets:

- If you are allergic (hypersensitive) to Losartan or any of its other ingredients
- If you are more than 3 months pregnant. (It is also better to avoid Losartan Potassium Tablets in early pregnancy)

*Before you start to take it:*

You must tell your doctor if you think you are pregnant. Losartan potassium tablets are 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 losartan potassium tablets:

- 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
- If your liver function is impaired

Tell your healthcare provider about all the medicines that you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Losartan potassium and some medicines may interact with each other, may not work as well, or may cause serious side effects. Your healthcare provider or pharmacist can tell you if it is safe to take losartan potassium tablets with your other medicines.

Do not start or stop any medicine while taking Losartan potassium tablets without talking to your healthcare provider first.

*Taking other medicines:*

Before starting losartan potassium tablets, tell your healthcare provider if you are taking:

- 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] or heparin)
- 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.

### **How to take Losartas tablets?**

#### *How much to take:*

#### Patients with high blood pressure:

Treatment usually starts with 50mg losartan orally once a day. The maximum effect is achieved 3 to 6 weeks after starting treatment. Some patients may receive further benefit by increasing the dose to 100 mg. If you have the impression that the effect of losartan is too strong or too weak, please talk to your doctor or pharmacist.

#### Patients with high blood pressure and diabetes:

Treatment usually starts with 50 mg losartan once a day. The dose may later be increased to 100 mg losartan 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 insulin and other commonly used medicines that decrease the level of glucose in the blood (e.g. sulphonylureas, glitazones and glucosidase inhibitors)

For patients with low blood volume (Intravascular volume depletion e.g. treated with high-dose diuretics):

Treatment should be started with 25mg once daily.

#### *When to take it:*

You should try to take your daily dose at about the same time each day. It is important that you continue to take losartan potassium tablets until your doctor tells you otherwise. Losartan potassium tablets can be taken with or without food.

#### *How long to take it:*

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

Do not stop taking your tablets if you are feeling well or experiencing side effects, unless your doctor tells you to do so. Treatment with losartan potassium is long-term and it should not be interrupted unless on medical advice.

#### *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 take too much (overdose):*

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.

### **While you are using Losartas tablets:**

#### *Things you must do:*

If you become pregnant while taking losartan potassium tablets, tell your doctor.

Tell all doctors, dentists, and pharmacists that you are taking losartan potassium tablets.

Visit your doctor regularly so that they can check on your progress.

#### *Things you must not do:*

Do not take losartan potassium tablets for any other complaints unless your doctor tells you to.

Do not stop taking losartan potassium tablets or lower the dosage without checking with your doctor.

#### *Things to be careful of:*

No studies on the effects on the ability to drive and use machines have been performed. Losartan potassium 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, losartan potassium 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:

The most common drug-related side effects were dizziness, asthenia / fatigue and vertigo.

The following adverse reactions have been reported;

*Hypersensitivity:* anaphylactic reactions, angioedema including swelling of the mouth or throat causing airway obstruction and / or swelling of the face, lips.

*Gastro-intestinal:* hepatitis, diarrhea, liver function abnormalities, vomiting

*Haematologic:* anaemia, thrombocytopenia

*Musculoskeletal:* myalgia, arthralgia

*Nervous system / psychiatric:* migraine, dysgeusia

*Respiratory:* cough

*Skin:* pruritus, erythroderma

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of Losartan potassium tablets. For more information, ask your healthcare provider or pharmacist.

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 [portal.bpfk.gov.my](http://portal.bpfk.gov.my) (Consumers → Reporting)

### **Storage and disposal of Losartan tablets.**

#### **Storage:**

Do not store above 25°C.  
Keep losartan potassium tablets out of the reach of children.

#### **Disposal:**

If your doctor tells you to stop taking losartan potassium tablets or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets left over.

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 Losartan tablets look like?*

Losartan 25mg tablet:  
White to off white, round, biconvex, film coated tablets with break line on one side and “25” debossing on other side.

Losartan 50mg tablet:  
White to off white, round, biconvex, film coated tablets with break line on one side and “50” debossing on other side.

Losartan 100mg tablet:  
White to off white, round, biconvex, film coated tablets plain on one side and “100” debossing on other side.

Losartan potassium tablets are packed in PVC/PVdC-Aluminum blister strip of 10 tablets. Each Carton contains 3 such strip (3 x 10 tablets).

#### *Active Ingredient*

Losartan Potassium 25mg, 50mg & 100mg

#### *Other Ingredients:*

Lactose Monohydrate  
Pregelatinised Starch  
Povidone (K-90)  
Isopropyl Alcohol  
Colloidal Anhydrous Silica  
Purified Talc  
Magnesium Stearate  
Hydroxypropyl cellulose (EF)  
HPMC E-15  
Polyethylene glycol 400  
Titanium dioxide  
Purified water

### **MAL. No.:**

Losartan 25mg tablet:

MAL10080046A

Losartan 50mg tablet:

MAL10080047A

Losartan 100mg tablet:

MAL10080048A

### **Manufacturer:**

INTAS PHARMACEUTICALS LTD.

Matoda-382210, Dist:  
Ahmedabad. India

### **Product registration holder:**

JETPHARMA SDN BHD  
No 13, Jalan Rajawali 2,  
Bandar Puchong Jaya,  
47100 Puchong,  
Selangor, Malaysia.

**Date of Revision: 23.7.2013**