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

- It is important to tell your doctor before taking Losartan Tablets:
  - if you have had a history of angioedema (swelling of the face, lips, throat, and/or tongue) (see also section 4 'Possible side effects')
  - if you suffer from heart failure with or without renal impairment or sepsis causing severe life threatening cardiac arrhythmias.
  - if you have diabetes or impaired kidney function (see pregnancy section).
  - if your liver function is severely impaired,
  - if you suffer from hepatic encephalopathy (a brain disease caused by liver failure)
  - if you are taking the following medicines while under treatment with Losartan Tablets:
    - non-steroidal anti-inflammatory drugs such as indomethacin, including Cox-2 inhibitors (medicines that reduce inflammation, for example celecoxib) and aliskiren (see also information under the headings 'Other medicines and Losartan Potassium' and 'Do not take Losartan Tablets'.)
    - if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.

Warning and precautions

Tell your doctor or pharmacist before taking Losartan Tablets.

- If you are taking the following medicines while under treatment with Losartan Tablets:
  - an ACE-inhibitor (for example enalapril, lisinopril, ramipril), in particular if you have diabetes-related kidney problems.
  - other medications that may increase serum potassium (see section 2 "Other medicines and Losartan Potassium")

- If you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.

Dosage in special patient groups

- If you are taking other medications that may increase serum potassium (see section 2 "Other medicines and Losartan Potassium").

- adult patients with high blood pressure.

- If you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.

- Losartan Tablets are unlikely to affect your ability to drive or use machines. However, as with many other medicines used to treat high blood pressure, a small number of people may feel dizzy or become drowsy.

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

- Losartan Tablets are not recommended for use in children under 6 years old as it has not been shown to work in this age group.

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

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

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

- Losartan Potassium 12.5 mg Film-Coated Tablets

- Losartan Potassium 100 mg Film-Coated Tablets

- Losartan Potassium 25 mg Film-Coated Tablets

- Losartan Potassium 50 mg Film-Coated Tablets

- Losartan Potassium 100 mg Film-Coated Tablets

Losartan Potassium 12.5 mg Film-Coated Tablets

- \**Losartan Potassium 12.5 mg FILM-COATED TABLETS**

- \**LOSARTAN POTASSIUM 100 mg FILM-COATED TABLETS**

- \**LOSARTAN POTASSIUM 25 mg FILM-COATED TABLETS**

- \**LOSARTAN POTASSIUM 50 mg FILM-COATED TABLETS**

- \**PACKAGE LEAFLET: INFORMATION FOR THE USER**


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**1. WHAT LOSARTAN TABLETS ARE AND WHAT THEY ARE 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 this increase by blocking these receptors, causing the blood vessels to relax which in turn lowers the blood pressures. Losartan slows the decrease of kidney function in patients with high blood pressure and type 2 diabetes.

Losartan Tablets are 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.
- if you have any further questions, ask your doctor, pharmacist or nurse.

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

- Losartan Tablets are unlikely to affect your ability to drive or use machines. However, as with many other medicines used to treat high blood pressure, a small number of people may feel dizzy or become drowsy.

- Losartan Tablets contain 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.

Losartan Tablets are unlikely to affect your ability to drive or use machines. However, as with many other medicines used to treat high blood pressure, a small number of people may feel dizzy or become drowsy.

- It is important to tell your doctor before taking Losartan Tablets:
  - if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.

- See also information under the heading "Do not take Losartan Tablets".

- If you are taking other medications that may increase serum potassium (see section 2 "Other medicines and Losartan Potassium").

- Losartan Tablets are likely to affect your ability to drive or use machines. However, as with many other medicines used to treat high blood pressure, a small number of people may feel dizzy or become drowsy.

- Losartan Tablets contain 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.

- Losartan Tablets are unlikely to affect your ability to drive or use machines. However, as with many other medicines used to treat high blood pressure, a small number of people may feel dizzy or become drowsy.

- If you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.

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

- Losartan Potassium 12.5 mg Film-Coated Tablets

- Losartan Potassium 100 mg Film-Coated Tablets

- Losartan Potassium 25 mg Film-Coated Tablets

- Losartan Potassium 50 mg Film-Coated Tablets

- Losartan Potassium 100 mg Film-Coated Tablets
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 Tablets). The doctor may increase the dose if blood pressure is not controlled.

Adult patients with high blood pressure and/or diabetes

Each Losartan potassium 25 mg Tablet contains 25 mg of losartan potassium.

Each Losartan potassium 50 mg Tablet contains 50 mg of losartan potassium.

Each Losartan potassium 100 mg Tablet contains 100 mg of losartan potassium.

Do not take any tablets that have passed the expiry date which is stated on the carton after Exp. The expiry date refers to the last day of that month expressed by the letters ‘Exp.’

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

Side effects in children are similar to those in adults. If you stop taking side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

Reporting of side effect

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

If you forget to take Losartan Tablets

Losartan Tablets are supplied as white, film-coated, round, biconvex tablets, scored on both sides.

Losartan Tablets are supplied as white, film-coated, round, biconvex tablets, quadrisected on one side.

Losartan Tablets are supplied as white, film-coated, oblong, biconvex tablets, scored on both sides.

Losartan Tablets are supplied as white, film-coated, round, biconvex tablets.

Each Losartan potassium 100 mg Tablet contains 100 mg of losartan potassium.

Each Losartan potassium 50 mg Tablet contains 50 mg of losartan potassium.

Each Losartan potassium 25 mg Tablet contains 25 mg of losartan potassium.

The doctor may advise a lower dose, especially when starting treatment in certain patients such as those treated with diuretics or other blood pressure-lowering medicines (e.g. duretics, calcium channel blockers, alpha- or beta-blockers, and centrally acting agents) as well as with insulin and other oral hypoglycaemic medicines that decrease the level of glucose in the blood (e.g. sulphonylureas, glitazones and glucosidase inhibitors).

Marketing Authorisation Holder and Manufacturer:

Desox-Pharma Ltd., 1 Stoney Hill, Drayton Fields, Daventry, Northamptonshire, NN11 8PQ, UK.

If you accidentally miss a daily dose, take the next dose as soon as you remember. 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, pharmacist or nurse.

4. POSSIBLE SIDE EFFECTS

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 Tablets until your doctor tells you otherwise.

If you take more Losartan Tablets than you should:

If you experience the following, stop taking Losartan tablets and tell your doctor immediately. You may need urgent medical attention or hospitalisation.

The doctor may increase the dose if blood pressure is not controlled.

Dosage in special patient groups

Daily doses of 25-50 mg administered once a day may be given to patients with mild to moderate heart failure.

The doctor may increase the dose if blood pressure is not controlled.

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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 Tablets until your doctor tells you otherwise. Losartan Tablets may be used.

A maximum dose of 150 mg losartan (for example, three tablets of Losartan 50 mg or one tablet each of Losartan 100 mg and Losartan 50 mg) may be given to patients with severe cardiac failure (e.g. during the first week, 25 mg daily. During the third week, 100 mg daily during the fourth week, 150 mg daily during the fifth week) to the maintenance dose as determined by your physician.

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

It is important that you continue to take Losartan Tablets until your doctor tells you otherwise.

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.

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In patients with heart failure, Losartan tablets may be used.

Common

The following side effects have been reported with losartan:

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 Tablets until your doctor tells you otherwise.

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

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In patients with heart failure, Losartan tablets may be used.

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