LORISTA FILM-COATED TABLET

Losartan potassium (50 mg, 100 mg)

What is in this leaflet

What *Lorista* is used for

Lorista is used:
- to treat adult patients with high blood pressure (hypertension).
- to protect the kidney in hypertensive type 2 diabetic patients with laboratory evidence of impaired renal function and proteinuria (a condition in which urine contains an abnormal amount of protein).
- in patients with high blood pressure and a thickening of the left heart wall, *Lorista* has been shown to decrease the risk of stroke.

How *Lorista* works

Lorista contains an active ingredient called losartan. 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 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 *Lorista*

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 *Lorista* in early pregnancy)

Before you start to use it
It is important to tell your doctor before taking *Lorista**:***
- if you have had a history of angiooedema (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 (see also Dosage in special patient groups)
- if your liver function is impaired (see section Dosage in special patient groups)

Special warnings about the excipients
Lorista contains lactose and is therefore not suitable for patients with the following medical problems: lactase deficiency, galactosemia or glucose-galactose malabsorption syndrome.

Taking other medicines
Please 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 *Lorista:*
- 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 medicines 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

How to use *Lorista*

How much to use
Always take *Lorista* exactly as your doctor has instructed you. Your doctor will decide on the appropriate dose of *Lorista*, depending on your condition and whether you are taking other medicines.

Adult patients with high blood pressure
Treatment usually starts with 50 mg losartan (one tablet *Lorista* 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 *Lorista* 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.

Adult patients with high blood pressure and type 2 diabetes
Treatment usually starts with 50 mg losartan (one tablet *Lorista* 50 mg) once a day. The dose may later be increased to 100 mg losartan (two tablets *Lorista* 50 mg) 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 with insulin and other commonly used medicines that decrease the level of glucose in the blood (e.g. sulfonylureas, glitazones and glucosidase inhibitors).

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.

When to use 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 *Lorista* exactly as your doctor has told you. *Lorista* may be taken with or without food. The tablets should be swallowed with a glass of water.

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

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

Lorista 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, *Lorista* 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).

The following side effects have been reported with *Lorista*:

Common:
- dizziness
- insomnia(sleeping disorder)
- fatigue
- too much potassium in the blood (hyperkalaemia)
- lack or loss of strength (asthenia)
- diarrhoea
- dyspepsia (indigestion)
- nausea
- abdominal pain
- muscle pain (myalgia)
- oedema/swelling
- chest pain

Uncommon:
- hives (urticaria)
- itching (pruritus)
- rash
- anaemia
- Henoch-Schönlein purpura (a disorder that causes inflammation and bleeding in the small blood vessels in your skin, joints, intestines and kidneys. It can be indicated with presence of purplish rash).
- migraine
- joint pain (arthralgia)
- mild increase in urea and creatinine serum levels

Rare:
- hepatitis
- liver function abnormalities
- increased hepatic enzyme activity
- anaphylactic reactions
- angioedema, swelling of the larynx and glottis causing airway obstruction and/or swelling of the face, lips, pharynx, and/or tongue

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 (Consumers →Reporting).

Storage and Disposal of *Lorista*

Storage
Keep out of the reach and sight of children.

Do not store above 25 °C.

Store in the original package in order to protect from moisture.

Do not use your medicine after the expiry date which is stated on the pack after 'EXP'. The expiry date refers to the last day of that month.

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
Lorista 50 mg film-coated tablets: round, slightly biconvex, white, bevel-edged, one-side-scored tablets. The score line is not intended for breaking the tablet.

Lorista 100 mg film-coated tablets: oval, slightly biconvex, white tablets.

Ingredients
Active ingredient:
Losartan potassium

Inactive ingredients:
Maize starch, pregelatinised starch, microcrystalline cellulose, colloidal anhydrous silica, magnesium stearate, powdered cellulose and lactose monohydrate in the tablet core, hypromellose, talc, propylene glycol

and titanium dioxide (E171) in the film-coating.

MAL numbers:
50 mg tablets: MAL11030006A
100 mg tablets: MAL11030007A

Manufacturer
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