LORISTA H/ LORISTA HD FILM-COATED TABLETS

Losartan potassium/Hydrochlorothiazide (50/12.5 mg, 100/25 mg)

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What *Lorista* is used for

Lorista is indicated for the treatment of high blood pressure when combined treatment is required.

How *Lorista* works

Lorista is a combination of an angiotensin II receptor antagonist (losartan) and a diuretic (hydrochlorothiazide).

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. Hydrochlorothiazide works by making the kidneys pass more water and salt. This also helps to reduce blood pressure.

Before you use *Lorista*

When you must not use it

Do not take *Lorista*

- if you are allergic (hypersensitive) to losartan, hydrochlorothiazide or to any of the other ingredients in this medicine
- if you are allergic (hypersensitive) to other sulfonamide-derived substances (e.g. other thiazides, some antibacterial drugs such as co-trimoxazole, ask your doctor if you are not sure)
- if you are more than 3 months pregnant. (It is also better to avoid *Lorista* in early pregnancy)
- if you have severely impaired liver function
- if you have severely impaired kidney function or your kidneys are not producing any urine
- if you have low potassium, low sodium or high calcium levels which cannot be corrected by treatment
- if you are suffering from gout

Before you start use it

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

- if you have previously suffered from swelling of the face, lips, throat or tongue
- if you take diuretics (water pills)
- if you are on a salt-restricted diet
- if you have or have had severe vomiting and/or diarrhoea
- if you have heart failure
- if your liver function is impaired (see section "*When you must not take it"*)
- if you have narrow arteries to your kidneys (renal artery stenosis) or only have one functioning kidney, or you have recently had a kidney transplant
- if you have 'aortic or mitral valve stenosis' (narrowing of the valves of the heart) or 'hypertrophic cardiomyopathy' (a disease causing thickening of heart muscle)
- if you are diabetic
- if you have had gout
- if you have or have had an allergic condition, asthma or a condition that causes joint pain, skin rashes and fever (systemic lupus erythematodus)
- if you have high calcium or low potassium levels or you are on a low potassium diet
- if you need to have an anaesthetic (even at the dentist) or before surgery, or if you are going to have tests to check your parathyroid function, you must tell the doctor or medical staff that you are taking losartan potassium and hydrochlorothiazide tablets
- 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)

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.

Diuretic agents such as the hydrochlorothiazide contained in *Lorista* may interact with other medicines.

Preparations containing lithium should not be taken with *Lorista* without close supervision by your doctor.

Special precautionary measures (e.g. blood tests) may be appropriate if you take potassium supplements, potassium- containing salt substitutes or potassium-sparing medicines, other diuretics ("water tablets"), some laxatives, medicines for the treatment of gout, medicines to control heart rhythm or for diabetes (oral agents or insulin).

It is also important for your doctor to know if you are taking:

- other medicines to reduce your blood pressure
- steroids
- pain killers
- medicine for treatment of fungal infections
- arthritis medicines
- medicines which relax your muscles
- sleeping tablets
- opioid medicines such as morphine
- 'pressor amines' such as adrenaline or
- other medicines from the same group
- oral agents for diabetes or insulins

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 losartan/hydrochlorothiazide combination depending on your condition and whether you are taking other medicines.

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The usual dose of losartan/hydrochlorothiazide combination for most patients with high blood pressure is 1 tablet of *Lorista H* per day to control blood pressure over the 24-hour period. This can be increased to 2 tablets once daily of *Lorista H* or changed to 1 tablet daily of *Lorista HD* (a stronger strength) per day.

The maximum daily dose is 2 tablets per day of *Lorista H* film-coated tablets or 1 tablet daily of *Lorista HD* film-coated tablets.

Use in children and adolescents (< 18 years)
There is no experience with the use of *Lorista* in children. Therefore, *Lorista* should not be given to children.

Patients with mild renal impairment may be given the usual dose of *Lorista H. Lorista H* tablets are not recommended in patients with severe renal impairment and in patients on hemodialysis.

The recommended initial dose of losartan for patients with hypovolemia (decrease in blood volume) is 25 mg once daily therefore treatment with *Lorista H* should not be initiated before treatment with diuretics is discontinued and hypovolemia improved.

When to use it
You can take *Lorista* with food or on an empty stomach.

Always take *Lorista* exactly as your doctor has told you. Take your medicine preferably in the morning. In order not to leave out any tablets, you should take the medicine at the same time every day.

How long to use it
Treatment with Lorista is usually long-term treatment.
The duration of treatment is not limited. 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 miss a dose, do not take an extra dose. Just resume your usual schedule.

If you use too much (overdose)
In case of an overdose, contact your doctor immediately so that medical attention may be given promptly.

Overdose can cause a drop in blood pressure, palpitations, slow pulse, changes in blood electrolyte level and acidity balance

While you are using it

Things you must do
You must tell your doctor if you think that 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.

Things you must not do
You are advised not to drink alcohol whilst taking these tablets: alcohol and *Lorista* tablets may increase each other's effects.

Dietary salt in excessive quantities may counteract the effect of *Lorista* tablets.

Things to be careful of
When you begin treatment with this medication, you should not perform tasks which may require special attention (for example, driving an automobile or operating dangerous machinery) until you know how you tolerate your medicine.

Side effects

Like all medicines, *Lorista* tablets can cause side effects, although not everybody gets them.

The following undesirable effects have been reported:
- Anapphylactic reactions, angioedema (including swelling of the larynx and glottis causing airway obstruction and/or swelling of the face, lips, pharynx and/or tongue), vasculitis (inflammation of the blood vessels – including Henoch-Schonlein purpura), cough, urticarial (itchy rash).

Additionally side effects that have been seen with one of the individual components and may be potential side effects with *Lorista H* or *Lorista HD* are the following:

Losartan
- dose-related orthostatic effects
- liver function abnormalities
- muscle pain
- migraine
- rash
- anaemia (reduction in red blood cells number)
- pruritus (itching)

Hydrochlorothiazide
- anorexia (eating disorder)
- gastric irritation
- nausea
- vomiting
- cramping
- diarrhea
- constipation
- jaundice
- inflammation of the pancreas
- inflammation of salivary gland
- vertigo (feeling of spinning)
- paraesthesiae (pins and needles)
- headache
- xanthopsia (a visual disturbance in which objects appear yellow)
- leucopenia (decrease in the number of white blood cells)
- agranulocytosis (a rare condition that occurs when the bone marrow does not make enough neutrophils, the white blood cells needed to fight infections)
- low platelet count

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- aplastic anaemia (bone marrow failure to produce blood cells)
- purpura ((bleeding underneath the skin which indicated by reddish-purple spot, which like a bruise)
- photosensitivity
- fever
- necrotising angiitis (inflammation of blood vessels that lead to the damage of blood vessels tissue)
- respiratory distress (including inflammation of lung tissue and fluid in the lungs)
- anaphylactic reactions (severe allergic reaction that may lead to death)
- toxic epidermal necrolysis (a rare and life-threatening skin condition)
- high blood sugar level
- excretion of glucose (sugar) in urine
- high level of uric acid in the blood
- electrolyte lmbalance (including low blood sodium level and low blood potassium level)
- kidney dysfunction
- interstitial nephritis (inflamed kidney)
- kidney failure
- muscle spasm
- weakness
- restlessness
- transient blurred vision

Laboratory tests

- high blood potassium level
- elevations of alanine transaminase (ALT), a type of liver enzyme (usually resolved upon discontinuation of therapy)
- decreases in haematocrit and haemoglobin

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 H 50 mg/12.5 mg: yellow, oval, slightly biconvex tablets with a score on one side. The score line is not intended for breaking the tablet.

Lorista HD 100 mg/25 mg: yellow, oval, slightly biconvex tablets.

Ingredients
Active ingredients:
Losartan potassium and hydrochlorothiazide.

Inactive ingredients:
Pregelatinized starch, microcrystalline cellulose, lactose monohydrate, magnesium stearate, hypromellose, macrogol 4000, quinoline yellow colour (E104), talc, titanium dioxide (E171).

MAL numbers:
Lorista H 50 mg/12.5 mg:
MAL12020017A

Lorista HD 100 mg/25 mg:
MAL12020018A

Manufacturer
KRKA, d.d., Novo mesto,
Šmarješka cesta 6,
8501 Novo mesto,
Slovenia

Product Registration Holder
Pahang pharmacy Sdn. Bhd,
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Malaysia

Date of revision
12/06/2015

Serial Number
BPFK(R4/1)080615/00146