

LORISTA H/ LORISTA HD FILM-COATED TABLETS

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

What is in this leaflet

1. What Lorista H and Lorista HD is used for
2. How Lorista H and Lorista HD works
3. Before you use Lorista H and Lorista HD
4. How to use Lorista H and Lorista HD a
5. While you are using it
6. Side effects
7. Storage and Disposal of Lorista H and Lorista HD
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What Lorista H and Lorista HD is used for

Lorista H and Lorista HD is a combination of an angiotensin II receptor antagonist (losartan) and a diuretic (hydrochlorothiazide). Losartan and hydrochlorothiazide work together to lower high 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 Lorista H and Lorista HD to help lower the risk of cardiovascular events, such as stroke.

How Lorista H and Lorista HD works

The losartan ingredient of Lorista H and Lorista HD lowers blood pressure by specifically blocking a substance called angiotensin II. Angiotensin II normally tightens your blood vessels. The losartan ingredient of Lorista H or Lorista HD allows them to relax. The hydrochlorothiazide ingredient of Lorista H and Lorista HD works by making your kidneys pass more water and salt. Together, losartan and hydrochlorothiazide lower high blood pressure. Although your doctor will be able to tell you that the medicine is working by measuring your blood pressure, you probably will feel no different while you are taking Lorista H or Lorista HD.

Why has my doctor prescribed Lorista H or Lorista HD?

Your doctor has prescribed Lorista H or Lorista HD because you have a

condition known as hypertension or high blood pressure. In patients with high blood pressure and a thickening of the left ventricle, losartan, often in combination with hydrochlorothiazide, reduces the risk of stroke and heart attack and helps patients live longer (see "Before you take Lorista H and Lorista HD.", "Use in Black patients with high blood pressure and a thickening of the left ventricle").

Before you use Lorista H and Lorista HD

- When you must not use it

Do not take Lorista H and Lorista HD

- 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 H and Lorista HD 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
- have diabetes and are taking a medicine called aliskiren to reduce blood pressure

- Before you start use it

Tell your doctor or pharmacist about any medical problems you have or have had, and about any allergies. Tell your doctor if you have recently suffered from excessive vomiting or diarrhea.

It is particularly important to tell your doctor if you have liver or kidney disease, gout, diabetes, lupus erythematosus, or if you are being treated with other diuretics (water tablets). In these cases, your doctor may need to adjust the dose of your medications.

Before surgery and anesthesia (even at the dentist's office), tell the doctor or dentist that you are taking Lorista H or Lorista HD, as there may be a sudden fall in blood pressure associated with the anesthesia.

Inform your healthcare providers before taking Lorista H or Lorista HD, if you have had skin cancer or if you develop an unexpected skin lesion during the treatment.

Treatment with hydrochlorothiazide, particularly long term use with high doses, may increase the risk of some types of skin and lip cancer (nonmelanoma skin cancer). Protect your skin from sun exposure and UV rays while taking Lorista H or Lorista HD.

Inform your healthcare providers before taking Lorista H or Lorista HD, if you experience a decrease in vision or eye pain. These could be symptoms of fluid accumulation in the vascular layer of the eye (choroidal effusion) or an increase of pressure in your eye and can happen within hours to weeks of taking Lorista H or Lorista HD.

This can lead to permanent vision loss, if not treated. If you earlier have had a penicillin or sulfonamide allergy, you can be at higher risk of developing this.

Inform your healthcare providers before taking Lorista H or Lorista HD, if you experienced breathing or lung problems (including inflammation or fluid in the lungs) following hydrochlorothiazide intake in the past. If you develop any severe shortness of breath or difficulty breathing after taking Lorista H or Lorista HD, seek medical attention immediately

- 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 H and Lorista HD may interact with other medicines.

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Preparations containing lithium should not be taken with Lorista H and Lorista HD 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
- medicines to treat cancer
- pain killers
- medicine for treatment of fungal infections
- arthritis medicines
- resins used for high cholesterol, such as colestyramine
- 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

Please also inform your doctor you are taking Lorista H or Lorista HD if you will be undergoing a radiographic procedure and will be given iodine contrast media.

How to use Lorista

- How much to use

High blood pressure

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.

Patients with high blood pressure and a thickening of the left ventricle

The usual starting dose is 50 mg of losartan once daily. If goal blood pressure is not reached with losartan 50 mg, your doctor may prescribe a combination of losartan and low dose hydrochlorothiazide (12.5 mg). Your doctor will increase the amounts of losartan and hydrochlorothiazide step by step until the dose that is right for you has been achieved.

- When to use it

Lorista H or Lorista HD can be taken with or without food. For convenience and to help you remember, try to take Lorista H or Lorista HD at the same time each day.

- How long to use it

Take Lorista H or Lorista HD every day, exactly as your doctor has instructed. It is important to continue taking Lorista H or Lorista HD for as long as your doctor prescribes it in order to maintain smooth control of your blood pressure.

- If you forget to use it

Try to take Lorista H or Lorista HD daily as prescribed. 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 composition, and dehydration.

While you are using it

- Things you must do

- Take your medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists treating you that you are taking Lorista H or Lorista HD.
- Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

- Do not stop taking the medicine unless advised by your doctor.
- Do not take any new medicines without consulting your doctor.
- Do not give Lorista H or Lorista HD to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Use in pregnancy and breastfeeding

The use of Lorista H or Lorista HD while you are pregnant or breastfeeding is not recommended.

Lorista H or Lorista HD can cause harm or death to an unborn baby. Talk to your doctor about other ways to lower your blood pressure if you plan to become pregnant. If you get pregnant while taking Lorista H or Lorista HD tell your doctor right away.

Use in children

There is no experience with the use of Lorista H or Lorista HD in children. Therefore, Lorista H or Lorista HD should not be given to children.

Use in the elderly

In general, Lorista H or Lorista HD works equally well in, and is equally well tolerated by most older and younger adult patients. Most older patients require the same dose as younger patients. Older patients should begin treatment with Lorista H 50/12.5 mg tablets.

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, losartan was shown to decrease the risk of stroke and heart attack, and help patients live longer. However, in this study, these benefits, when compared to another antihypertensive medicine called atenolol, did not apply to Black patients.

Driving and using machines

Almost all patients can, but 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.

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Lorista H and Lorista HD contain lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Side effects

Any medicine may have unintended or undesirable effects, so-called side effects. In most patients, losartan/hydrochlorothiazide is well tolerated. Side effects may include nausea, vomiting, cramping, diarrhoea, constipation, headache, weakness, dizziness, fatigue, hives, rash, taste alteration, transient blurred vision, or increased sensitivity of the skin to sun. Another side effect may be a feeling of dizziness or light-headedness due to a sudden drop in blood pressure when standing up quickly.

With frequency “not known” decrease in vision or pain in your eyes due to high pressure (possible signs of choroidal effusion: an abnormal building of liquid in your eye that may result in vision changes; or acute angle-closure glaucoma: a rapid increased pressure in your eyes, eye pain. If left untreated, it may lead to permanent vision loss; or acute myopia: sudden nearsightedness or blurred vision) and skin and lip cancer (non-melanoma skin cancer) have been reported. Your doctor or pharmacist has a more complete list. Tell your doctor or pharmacist promptly about these or any other unusual symptoms.

If you develop an allergic reaction involving swelling of the face, lips, throat and/or tongue which may cause difficulty in breathing or swallowing, stop taking losartan/hydrochlorothiazide and contact your doctor immediately.

If you develop an acute respiratory distress (signs include severe shortness of breath, fever, weakness, and confusion) stop taking losartan/hydrochlorothiazide and contact your doctor immediately.

You may report any side effects or adverse drug reactions directly to The National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.moh.gov.my [Consumers - > Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Lorista

- Storage

Keep out of the reach and sight of children.

Do not store above 30°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:
MAL12020017AZ

Lorista HD 100 mg/25 mg:
MAL12020018AZ

Manufacturer

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

Product Registration Holder

Pahang pharmacy Sdn. Bhd,
Lot 5979, Jalan Teratai,
5 ½ Miles, Off Jalan Meru,
41050 Klang, Selangor,
Malaysia

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