

PACKAGE LEAFLET: INFORMATION FOR THE USER

Lopril

Lopril H 10mg/12.5mg Tablets; Lopril H 20mg/12.5mg Tablets; Lopril H Plus 20mg/25mg Tablets

LISINOPRIL AND HYDROCHLOROTHIAZIDE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

• Keep this leaflet • You may need to read it again • If you have any further questions, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •

What is in this leaflet?

1. What Lopril H is and what it is used for
2. What you need to know before you take Lopril H
3. How to take Lopril H
4. Possible Side Effects
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1. WHAT LOPRIL H IS AND WHAT IT IS USED FOR

Each Lopril H tablet contains lisinopril and hydrochlorothiazide.

Lisinopril belongs to the group of drugs called angiotensin converting enzyme inhibitors (ACE inhibitors). These medicines work by helping to widen your blood vessels to make it easier for your heart to pump blood through them to all parts of your body.

Hydrochlorothiazide belongs to the group of drugs called diuretics (water tablets). These medicines increase the amount of water you lose in your urine and therefore reduce the amount of fluid in your blood vessels.

Lopril H is used to treat high blood pressure. If high blood pressure is left uncontrolled it can increase the risk of heart disease or a stroke. Lopril H works by lowering your blood pressure which reduces this risk.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE LOPRIL H

Do not take Lopril H tablets if:

- You have previously been treated with a medication in the same group of medicines as Lopril H (ACE inhibitors) and have had allergic reactions with symptoms such as swelling of the face, lips, tongue and/or throat with difficulty in swallowing or breathing.

- You have ever had an allergic reaction to this medicine or to any sulphonamide-derived drugs. (Ask your doctor if you are not sure what sulphonamide-derived drugs are).
- You suffer from hereditary or idiopathic angioedema (very bad swelling of your skin especially around the eyes, lips, nose, tongue, voicebox (larynx) or hands). This means you were either born with this illness or your doctor does not know what causes it.
- If you are more than 3 months pregnant. (It is also better to avoid Lopril H in early pregnancy – see pregnancy section.)
- You have severe liver disease
- You suffer from an inability to pass water (anuria).
- You have a specific type of heart disease called aortic stenosis.
- You have high levels of potassium in the blood.
- You have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.

If any of the above affects you, or you are unsure if they do, tell your doctor who will be able to advise you.

Warnings and precautions

You must tell your doctor if:

- You have or have had any medical problems or any allergies.
- You suffer from liver, kidney or heart disease.
- You are undergoing dialysis.
- You have had a kidney transplant
- You have recently suffered from excessive vomiting or diarrhoea.
- You have been told you have abnormal levels of the following natural body chemicals: potassium, calcium, urea, creatinine, uric acid, cholesterol or triglycerides.
- You have gout.
- You have a condition which causes joint pain, skin rashes and fever (called systemic lupus erythematosus).
- You develop jaundice (yellowing of the skin and/or the whites of the eyes).
- You are diabetic (your doctor may want to monitor you for the first month of treatment).
- You think you are (or might become) pregnant. Lopril H is 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 (see pregnancy section).

Tell your doctor if you are taking any of the following medicines used to treat high blood pressure:

- an angiotensin II receptor blocker (ARBs) (also known as sartans – for example valsartan, telmisartan, irbesartan), in particular if you have diabetes-related kidney problems
- aliskiren

Your doctor may check your kidney function, blood pressure and the amount of electrolytes (e.g., potassium) in your blood at regular intervals.

See also information under the heading “Do not take Lopril H tablets if”

If you are about to have desensitisation treatment, that is treatment to reduce the effects of an allergy to bee or wasp stings, you should tell the doctor who is treating you that you are taking Lopril H.

If you are about to have a treatment for the removal of cholesterol from your blood by a machine, (called LDL apheresis), you should tell the doctor who is treating you that you are taking Lopril H.

If you are due to have surgery

Before surgery and anaesthesia (even at the dentists) you should tell the doctor or dentist that you are taking Lopril H as there may be a sudden fall in blood pressure.

Children and adolescents

Lopril H is not for use in children

Taking Lopril H with other medicines

Always tell your doctor about other medicines you may be taking or have recently taken including those obtained without a prescription. Some medicines can have an effect on each other's actions.

Your doctor may need to change your dose and/or to take other precautions:

- if you are taking an angiotensin II receptor blocker (ARB) or aliskiren (see also information under the headings "Do not take Lopril H tablets if:" and "Warnings and Precautions").

It is especially important that you tell your doctor if you are taking medicines for:

- Diabetes such as insulin or tablets to lower blood sugar (e.g. aliskiren).
- Mental disorders, such as lithium or antipsychotics.
- Gout (such as allopurinol).
- The treatment of cancer.
- Abnormal heart rhythms (e.g. procainamide or sotalol).
- Indigestion (e.g. antacids).
- Hypertension, shock, heart failure, asthma or allergies (e.g. ephedrine, noradrenaline or epinephrine (adrenaline)).
- Helping you to sleep or reduce anxiety (sedatives).
- High blood cholesterol (medicines called colestyramine or colestipol).

Or if you are taking:

- Any diuretics (water tablets). If you are already taking a diuretic your doctor may tell you to reduce the dose of the diuretic, or even tell you to stop taking them, before you start taking Lopril H.
- Steroids to treat various conditions including rheumatism, arthritis, allergic conditions, certain skin disease, asthma or a blood disorder.
- Non-steroidal anti-inflammatory drugs (NSAID) (a type of pain killer e.g. indomethacin).
- A narcotic pain killer (e.g. codeine, dextropoxyphene, diamorphine, morphine, pentazocine, pethidine).
- Medicines that suppress your immune system following surgery (e.g. ciclosporin) or some autoimmune disorder such as rheumatoid arthritis
- ACTH to test whether your adrenal glands are working properly.
- Potassium supplements, potassium-sparing agents, potassium-containing salt substitutes or are on a low-salt diet.
- Antidepressants and/or antipsychotics.
- Gold therapy which is used to treat arthritis.
- Muscle relaxant used during surgery (e.g. tubocurarine chloride).
- Trimethoprim (used to treat urinary infections).
- An mTOR inhibitor (e.g. temsirolimus, sirolimus, everolimus).

Please note that when you are taking Lopril H it may affect any tests your doctor may perform on blood or urine samples. Please remind your doctor you are taking Lopril H if they ever want to carry out such a test.

Pregnancy and Breastfeeding

Pregnancy

You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking Lopril H before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Lopril H. Lopril H is not recommended during 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.

Breastfeeding

Tell your doctor if you are breast-feeding or about to start breast-feeding. Lopril H 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 newborn, or was born prematurely.

Taking with Food and Drink

You can drink alcohol while taking this medicine, however, medicines used to reduce blood pressure taken together with alcohol may cause dizziness or light-headedness. If you are concerned about how much alcohol you can drink while you are taking Lopril H you should discuss this with your doctor.

Driving or operating machinery

Lopril H may have a mild effect on your ability to drive or operate machinery, especially when treatment is first started or when the dose is changed and if used with alcohol. When driving or operating machinery it should be taken into account that occasionally dizziness or tiredness may occur.

3. HOW TO TAKE LOPRIL H

Take Lopril H as your doctor has instructed. Your pharmacist may also help if you are not sure.

The usual dosage is one or two tablets taken once a day, taken at the same time each day.

Lopril H can be taken at any time of the day before, during, or after a meal. Choose a time that is convenient for you and take your tablet at this time every day.

Be especially careful when you take your first dose or if your dose is increased. Let your doctor know as soon as possible if you feel any dizziness or light-headedness.

The effect of Lopril H tablets lasts 24 hours so you only need to take the tablets once a day.

Take the tablet for the day marked on the calendar pack. This will help you to remember whether you have taken your tablet for that day.

Keep taking your tablets until your doctor tells you to stop.

If you take more Lopril H than you should

If you take too many tablets seek medical attention immediately. The most likely symptoms of overdose would be a feeling of lightheadedness or dizziness due to a drop in blood pressure.

If you forget to take Lopril H

If you forget to take a tablet, DO NOT WORRY – just take the next day's tablet when it is due. DO NOT take a double dose to make up for the forgotten dose.

If you have any further questions on the use of this product, ask your Doctor or Pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Lopril H can cause side effects, although not everybody gets them.

The following terms are used to describe how often side effects have been reported:

- **Very common** (occurring in 1 or more of 10 patients treated)
- **Common** (occurring in 1 or more of 100 and less than 1 of 10 patients treated)
- **Uncommon** (occurring in 1 or more of 1000 and less than 1 of 100 patients treated)
- **Rare** (occurring in 1 or more of 10000 and less than 1 of 1000 patients treated)
- **Very rare** (occurring in less than 1 of 10000 patients treated including isolated reports).

Stop taking the tablets and tell your doctor immediately if you get any of the following symptoms: swelling of the face, lips, tongue and/or throat with difficulty in swallowing or breathing. These may be signs of an allergic reaction.

The following side effects have been reported:

Common: dizziness, headache, feeling of light headedness when standing up quickly, due to a drop in blood pressure (orthostatic hypotension) which may result in fainting, cough, diarrhoea, vomiting, kidney problems.

Uncommon: abnormal sensations such as 'pins and needles', spinning sensation, taste disturbance, changes in mood, sleep disturbances, heart attacks or stroke in some patients (which may be due to a drop in blood pressure), fast or irregular heartbeat, Raynaud's syndrome (symptoms include cold fingers and toes), sneezing,

nausea, abdominal pain, indigestion, rash, itchiness, impotence, weakness and tiredness, alterations in some laboratory blood tests.

Rare: mental confusion, dry mouth, hives and itching, hair loss, redness of the skin, high levels of urea in the blood, kidney problems or failure, breast enlargement in men, low levels of sodium in the blood, which may cause weakness, tiredness, headache, feeling sick, being sick (vomiting) and cramps.

Very rare: There have been very rare reports of blood disorders which may cause fever or chills, sore throats, ulcers in your mouth or throat, unusual bleeding or unexplained bruises. Swollen lymph nodes, low blood sugar, bronchitis, painful sinuses, difficulty breathing, inflammation of the pancreas, hepatitis (causing nausea, fever and dark urine), jaundice (yellowing of the skin and/or whites of eyes), liver failure, profuse sweating, blisters, skin problems including redness and shedding of skin and painful areas, change in urine volume.

Very rarely, it has been reported that in some patients the undesirable development of hepatitis has progressed to hepatic failure. If you develop jaundice, you should tell your doctor straight away.

A condition with a group of symptoms including fever, muscle and joint pain and inflammation of the blood vessels has been reported. The skin may also be sensitive to light and a rash may occur.

Other side effects (frequency unknown): depression, pain and swelling of the salivary glands, loss of appetite (anorexia), presence of sugar in the urine, increased cholesterol, gout, restlessness, transient blurred vision, vertigo (spinning sensation), fluid on the lungs, constipation, sensitivity to light, unusual bleeding or bruising under the skin.

If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist immediately. It will help if you make a note of what you experienced, when it started and how long it lasted.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE LOPRIL H

Do not store your tablets above 25°C.

Store in the original packaging.

Please check the expiry date of the product, shown on the carton and on the blister pack. Do not use after the month stated.

Keep your medicines out of the reach of children.

If you are told to stop taking this medicine, return any unused tablets to your pharmacist.

This leaflet was last revised in October 2015