

PACKAGE LEAFLET

Package leaflet: Information for the user

Lisinopril/Hydrochlorothiazide 10 mg/12.5 mg Tablets **Lisinopril/Hydrochlorothiazide 20 mg/12.5 mg Tablets**

Lisinopril and hydrochlorothiazide

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

1. What Lisinopril/Hydrochlorothiazide is and what it is used for
2. What you need to know before you take Lisinopril/Hydrochlorothiazide
3. How to take Lisinopril/Hydrochlorothiazide
4. Possible side effects
5. How to store Lisinopril/Hydrochlorothiazide
6. Contents of the pack and other information

1. What Lisinopril/Hydrochlorothiazide is and what it is used for

Lisinopril/Hydrochlorothiazide is used to treat high blood pressure (hypertension). It contains two medicines called lisinopril and hydrochlorothiazide which act together to lower your blood pressure.

Lisinopril belongs to a group of medicines called Angiotensin Converting Enzyme (ACE) inhibitors. ACE inhibitors lower blood pressure by widening your blood vessels. This allows the blood to flow more easily and reduces the effort needed to pump blood around the body.

Hydrochlorothiazide belongs to the group of medicines called thiazide diuretics (water tablets). The medicine works by helping your body to get rid of water and salts (like sodium) by increasing the amount of urine made by your kidneys.

Lisinopril/Hydrochlorothiazide is used to treat patients whose blood pressure is not adequately controlled by lisinopril alone or hydrochlorothiazide alone.

If high blood pressure is left untreated it can increase the risk of heart disease or stroke. Lisinopril/Hydrochlorothiazide works by lowering your blood pressure, which reduces this risk.

2. What you need to know before you take Lisinopril/Hydrochlorothiazide

Do not take Lisinopril/Hydrochlorothiazide

- if you are allergic to lisinopril and/or hydrochlorothiazide or any of the other ingredients of Lisinopril/Hydrochlorothiazide (listed in section 6).
- if you are allergic to ACE inhibitors or medicines containing a sulphonamide group (e.g. some antibiotics). If you are not sure if this applies to you, please ask your doctor.
- if you have had a sudden severe allergic reaction which caused skin rashes, breathing or swallowing problems or itchy skin, especially if this followed treatment with an ACE

inhibitor. The allergic reaction may have caused sudden swelling of the hands, feet, ankles, face, lips, tongue or throat.

- if you or a family member has had a severe allergic reaction of an unknown cause. This might indicate a condition called hereditary angioedema and could make you more prone to the swelling described above. If you are not sure if this applies to you, please ask your doctor.
- if you are not passing urine (anuria) or have severe kidney problems.
- if you have severe liver problems.
- if you are more than 3 months pregnant. (It is also better to avoid Lisinopril/Hydrochlorothiazide in early pregnancy – see the sections on ‘Pregnancy and breast-feeding’).
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.

If any of the above applies to you, or you are unsure if they do, talk to your doctor or pharmacist or nurse before taking Lisinopril/Hydrochlorothiazide.

Warnings and precautions

Talk to your doctor or pharmacist or nurse before taking Lisinopril/Hydrochlorothiazide:

- if you have a narrowing (stenosis) of the aorta (an artery in your heart), mitral valve (a valve in the heart) or the kidney artery.
- if you have an increase in the thickness of the heart muscle (known as hypertrophic cardiomyopathy).
- if you are suffering from heart failure and are taking medicines called ACE inhibitors.
- if you have problems with your blood vessels (collagen vascular disease).
- if you have low blood pressure. You may notice this as feeling dizzy or light-headed, especially when standing up.
- if you have kidney problems or you are having kidney dialysis or you have had a kidney transplant.
- if you have liver problems.
- if you have diabetes.
- 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
- if you are taking any of the following medicines, the risk of angioedema (rapid swelling under the skin in areas such as the throat) is increased:
 - sirolimus, everolimus and other medicines belonging to the class of mTOR inhibitors (used to avoid rejection of transplanted organs)

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 Lisinopril/Hydrochlorothiazide”

- if you have recently had diarrhoea or vomiting (being sick).
- if you are on a salt restricted diet.
- if you have high levels of cholesterol and you are having a treatment called ‘LDL apheresis’.
- if you have ever had a condition called systemic lupus erythematosus (SLE).
- if you are of black origin as Lisinopril/Hydrochlorothiazide may be less effective. You may also more readily get the side effect ‘angioedema’ (a severe allergic reaction with swelling of the hands, feet, ankles, face, lips, tongue or throat).

You must tell your doctor if you think you are **(or might become)** pregnant.

Lisinopril/Hydrochlorothiazide 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 the sections on ‘Pregnancy and breast-feeding’).

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking Lisinopril/Hydrochlorothiazide.

Treatment for allergies such as insect stings

Tell your doctor if you are having or are going to have treatment to lower the effects of an allergy such as insect stings (desensitisation treatment). If you take Lisinopril/Hydrochlorothiazide while you are having this treatment, it may cause a severe allergic reaction.

Operations

If you are going to have an operation (including dental surgery) tell the doctor or dentist that you are taking Lisinopril/Hydrochlorothiazide. This is because you can get low blood pressure (hypotension) if you are given certain local or general anaesthetics while you are taking Lisinopril/Hydrochlorothiazide.

Other medicines and Lisinopril/Hydrochlorothiazide

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because Lisinopril/Hydrochlorothiazide can affect the way some medicines work and some medicines can have an effect on Lisinopril/Hydrochlorothiazide.

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 Lisinopril/Hydrochlorothiazide” and “Warnings and precautions”).

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- other water tablets (diuretics) e.g. amiloride, triamterene, spironolactone.
- other medicines to treat high blood pressure (e.g. beta-blockers).
- nitrates (used for conditions like angina).
- lithium and other medicines used to treat depression and other mental illnesses.
- pain killers called non-steroidal anti-inflammatory drugs (NSAIDs) used to treat pain and inflammation e.g. indomethacin.
- high doses (more than 3 grams each day) of aspirin (acetylsalicylic acid).
- medicines that can increase the amount of potassium in the blood such as potassium tablets, heparin, **co-trimoxazole (also known as trimethoprim/sulfamethoxazole)**, potassium sparing diuretics or salt substitutes that have potassium in them.
- calcium salts.
- allopurinol (used for the treatment of gout).
- medicines to treat asthma.
- medicines to treat nose or sinus congestion or other cold remedies (including those you can buy in the pharmacy).
- corticosteroids (steroid medicines used to treat certain conditions such as rheumatism, arthritis, allergic conditions, asthma or certain blood disorders).
- corticotropin (a hormone).
- lovastatin (to lower cholesterol).
- medicines to suppress the body’s immune response (immunosuppressants, such as ciclosporin).
- medicines which are most often used to avoid rejection of transplanted organs (sirolimus, everolimus and other medicines belonging to the class of mTOR inhibitors). See section “Warnings and precautions”.
- colestyramine and colestipol (to lower cholesterol, prevent diarrhoea or reduce itching).
- insulin or other antidiabetic medicines that you take by mouth e.g. gliclazide, metformin.
- procainamide, amiodarone or sotalol (used to treat abnormal heart rhythms).
- cardiac glycosides (to treat heart failure).

- medicines that contain gold, such as sodium aurothiomalate, which may be given to you as an injection.
- amphotericin B injection (to treat fungal infections).
- carbenoxolone (to treat ulcers or inflammation in the gullet or in and around the mouth).
- medicines to treat constipation (stimulant laxatives).
- muscle relaxants such as tubocurarine.
- trimethoprim (an antibiotic).
- dextran sulphate (used in the treatment called 'LDL apheresis' to lower cholesterol).
- chemotherapy for cancer (cytostatics).
- other medicines known to have an effect on the heart called Torsades des pointes.

Simultaneous treatment with tissue plasminogen activators (medicines used to dissolve blood clots) may increase the risk of localised swelling in your face, mouth or in other parts of your body.

Lisinopril/Hydrochlorothiazide with food, drink and alcohol

You can take Lisinopril/Hydrochlorothiazide with or without food. Your ability to drive or use machines may be reduced if you drink alcohol while taking these tablets (see the section on 'Driving and using machines').

Pregnancy and breast-feeding

You must tell your doctor if you think you are **(or might become)** pregnant. Your doctor will normally advise you to stop taking Lisinopril/Hydrochlorothiazide before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Lisinopril/Hydrochlorothiazide. Lisinopril/Hydrochlorothiazide 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 breast-feeding or about to start breast-feeding.

Lisinopril/Hydrochlorothiazide 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.

Driving and using machines

This medicine may cause occasional dizziness or tiredness which may have an effect on your ability to drive or use machines, especially at the start of treatment or when the dose is adjusted, or in combination with alcohol. If this happens to you, do not drive or use any tools or machines. You must wait to see how your medicine affects you before trying these activities. Occasionally, dizziness or tiredness may occur when driving vehicles or operating machinery.

3. How to take Lisinopril/Hydrochlorothiazide

Dosage

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Once you have started taking Lisinopril/Hydrochlorothiazide your doctor may take blood tests. Your doctor may then adjust your dose so you take the right amount of medicine for you.

Taking your medicine

Swallow the tablet with a drink of water.

Try to take your tablets at the same time each day. It does not matter if you take Lisinopril/Hydrochlorothiazide before or after food.

Keep taking Lisinopril/Hydrochlorothiazide for as long as your doctor tells you to, it is a long term treatment. It is important to keep taking Lisinopril/Hydrochlorothiazide every day.

Taking your first dose

Take special care when you have your first dose of Lisinopril/Hydrochlorothiazide or if your dose is increased. It may cause a greater fall in blood pressure than later doses. This may make you feel dizzy or light-headed. If this happens, it may help to lie down. If you are concerned, please talk to your doctor as soon as possible.

Adults

The recommended dose is one tablet once a day. Your doctor will prescribe the tablet that is the right strength for you. If necessary, your doctor may increase your dose to two tablets once a day. The maximum dose is 40 mg lisinopril /25 mg hydrochlorothiazide.

Use in children

Lisinopril/Hydrochlorothiazide is not recommended for use in children.

If you take more Lisinopril/Hydrochlorothiazide than you should

If you take more Lisinopril/Hydrochlorothiazide than prescribed by your doctor, talk to a doctor or go to a hospital immediately.

Take the medicine pack with you so that the tablets can be identified.

If you forget to take Lisinopril/Hydrochlorothiazide

If you forget to take a dose, take it as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose.

Do not take a double dose to make up for a forgotten dose.

If you stop taking Lisinopril/Hydrochlorothiazide

Do not stop taking your tablets, even if you are feeling well, unless your doctor tells you to.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Lisinopril/Hydrochlorothiazide contains two medicines: lisinopril and hydrochlorothiazide. The following side effects have been seen with these individual medicines. This means they could also happen with Lisinopril/Hydrochlorothiazide.

Your doctor may take blood samples from time to time to check whether Lisinopril/Hydrochlorothiazide has had any effect on your blood.

Possible side effects with lisinopril

Severe allergic reactions (rare, may affect up to 1 in 1,000 people)

If you have a severe allergic reaction, **stop taking Lisinopril/Hydrochlorothiazide and see a doctor immediately**. The signs may include sudden onset of:

- Swelling of your face, lips, tongue or throat. This may make it difficult to swallow.
- Severe or sudden swelling of your hands, feet or ankles.
- Difficulty breathing.
- Severe itching of the skin (with raised lumps).

Severe skin reactions (very rare, may affect up to 1 in 10,000 people)

- Blistering of the skin and surrounding surfaces.
- Skin rash, which may blister, and looks like small targets (central dark spots surrounded by a paler area, with dark ring around the edge).
- A widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens Johnson Syndrome).
- A widespread rash with blisters and skin peeling on much of the body surface.

Severe liver problems (very rare, may affect up to 1 in 10,000 people)

The signs may include:

- Yellowing of your skin or eyes, dark coloured urine or a loss of appetite, nausea, vomiting, feeling generally unwell, fever, itching.

If you experience severe skin reactions or severe liver problems, **see a doctor immediately.**

Other possible side effects:

Common (may affect up to 1 in 10 people):

- Headache.
- Feeling dizzy or light-headed, especially if you stand up quickly.
- Fainting.
- Diarrhoea.
- Being sick (vomiting).
- Cough.
- Kidney problems (shown in a blood test).

Uncommon (may affect up to 1 in 100 people)

- Mood changes including feeling depressed.
- Tingling feeling such as 'pins and needles'.
- Spinning feeling (vertigo).
- Changes in the way things taste.
- Difficulty in sleeping.
- Heart attack or stroke.
- Fast or irregular heart beat.
- Numbness, tingling and change of colour in your fingers or toes.
- Runny or blocked nose.
- Feeling sick (nausea).
- Stomach pain and indigestion.
- Changes in blood tests that check how the liver is working.
- Rash.
- Itching.
- Being unable to get an erection (impotence).
- Feeling weak.
- Feeling tired.
- Increased levels of certain substances in your blood (urea, creatinine or potassium).

Rare (may affect up to 1 in 1,000 people)

- Decrease in the oxygen carrying substance in the blood. The signs may include feeling tired and pale skin.
- Feeling confused.
- Changes in the way things smell.
- Dry mouth.
- Skin rash with dark red, raised, itchy bumps (hives).

- Hair loss (alopecia).
- Psoriasis (a skin problem).
- Excessive release of antidiuretic hormone which leads to symptoms such as weakness, tiredness, confusion or fluid retention.
- Infection of the blood.
- Kidney failure.
- Enlarged breasts in men.
- Low levels of sodium in the blood, which may cause weakness, tiredness, headache, feeling sick, being sick (vomiting) and cramps.

Very rare (may affect up to 1 in 10,000 people):

- Problems with your bone marrow or a reduced number of blood cells and/or platelets in your blood. You may notice tiredness, an infection (which may be serious), fever, feeling breathless or that you bruise or bleed more easily.
- Destruction of red blood cells. The signs may include tiredness, headaches, being short of breath when exercising, dizziness, looking pale and yellowing of the skin and/or eyes.
- Swollen glands (lymph nodes).
- Increased immune response (autoimmune disease).
- Low levels of sugar in your blood (hypoglycaemia). The signs may include feeling hungry or weak, sweating and a fast heart beat.
- Suddenly feeling wheezy or short of breath (bronchospasm).
- Lung inflammation (which may make you feel breathless).
- A feeling of pain and fullness behind your cheeks and eyes (sinusitis).
- Eosinophilic pneumonia. The signs include a combination of the following:
 - sinusitis
 - feeling like you have flu
 - feeling more and more breathless
 - pain in the area of your stomach or gut
 - skin rash
 - a feeling of 'pins and needles' or numbness of your arms or legs.
- Inflammation of the pancreas. This causes moderate to severe pain in the stomach.
- Swelling of the lining of the gut. This may cause sudden stomach pain, diarrhoea or make you be sick (vomit).
- Excessive sweating.
- Passing less water (urine) than normal or passing no water.
- Unusual skin reaction called cutaneous pseudolymphoma. Symptoms include skin lesions, sometimes with fever, damage to blood vessels causing red or purple spots in the skin, muscle and joint pain, rash, sensitivity to sunlight and increases in the numbers of some blood cells (shown in blood tests).

Not known (frequency cannot be estimated from the available data):

- Seeing, feeling or hearing things that are not there (hallucinations).
- Flushing.

Possible side effects with hydrochlorothiazide

Not known (frequency cannot be estimated from the available data)

Severe skin reactions

- A widespread rash with blisters and skin peeling on much of the body surface.

Other possible side effects:

- Inflammation of a salivary gland.

- Problems with your bone marrow or a reduced number of blood cells and/or platelets in your blood. You may notice tiredness, an infection (which may be serious), fever, feeling breathless or that you bruise or bleed more easily.
- Destruction of red blood cells. The signs may include tiredness, headaches, being short of breath when exercising, dizziness, looking pale and yellowing of the skin and/or eyes.
- Decrease or loss of appetite.
- An increase in the amount of sugar (glucose) in your blood.
- Sugar in your urine.
- An increase in the amount of uric acid in your blood.
- Altered levels of substances in your blood (for example low sodium, magnesium, chloride and potassium). You may notice muscle weakness, thirst, 'pins and needles', cramps or feeling sick.
- Raised or high levels of fats in your blood (including cholesterol).
- Painful, swollen joints (these could be signs of gout).
- Feeling restless.
- Depression.
- Difficulty sleeping.
- Tingling feelings such as 'pins and needles'.
- Feeling light headed.
- Blurred vision for a short time or changes to your vision that can make things look yellow, high pressure in the eye. Severe eye pain with redness and sudden blurred vision. If you have a suddenly painful red eye, tell your doctor immediately; you may need treatment to avoid permanent loss of vision.
- A spinning feeling (vertigo).
- Feeling faint (especially when standing up).
- Damage to blood vessels causing red or purple spots in the skin.
- Difficulty breathing. You may feel breathless if your lungs get inflamed or have fluid on them.
- Stomach irritation.
- Diarrhoea.
- Constipation.
- Inflammation of the pancreas. This causes moderate to severe pain in the stomach.
- Yellowing of your skin or the whites of your eyes (jaundice).
- Skin problems including rash caused by sensitivity to sunlight, rash, hives (urticaria), activating or worsening of existing lupus conditions or appearance of unusual skin reactions.
- Allergic reactions.
- Muscle cramps and muscle weakness.
- Kidney problems which may be severe (shown in blood tests).
- Fever.
- Weakness.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

HPRA Pharmacovigilance,

Earlsfort Terrace,

IRL- Dublin 2;

Tel: +353 1 6764971;

Fax: +353 1 6762517.

Website: www.hpra.ie;

E-mail: medsafety@hpra.ie

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

5. How to store Lisinopril/Hydrochlorothiazide

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

Do not use this medicine after the expiry date which is stated on the carton and blister after 'EXP'. The expiry date refers to the last day of that month.

Lisinopril/Hydrochlorothiazide supplied in bottle packs should be used within 30 days after first opening.

This medicinal product does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Lisinopril/Hydrochlorothiazide contains

- The active substances are lisinopril (as dihydrate) and hydrochlorothiazide
Lisinopril/Hydrochlorothiazide 10mg/12.5mg: Each tablet contains 10 mg of lisinopril and 12.5 mg of hydrochlorothiazide.
Lisinopril/Hydrochlorothiazide 20mg/12.5mg: Each tablet contains 20 mg of lisinopril and 12.5 mg of hydrochlorothiazide
- The other ingredients are calcium hydrogen phosphate dihydrate, mannitol (E421), starch pregelatinised, croscarmellose sodium, povidone (K29/32), cellulose microcrystalline (E460), colloidal anhydrous silica, magnesium stearate/sodium laurilsulfate. The 10 mg/12.5 mg strength tablets also contain iron oxide red and iron oxide yellow.

What Lisinopril/Hydrochlorothiazide looks like and contents of the pack

Lisinopril/Hydrochlorothiazide 10 mg/12.5 mg Tablets are peach, mottled, round, biconvex tablets debossed with "LH1" on one side of the tablet and "M" on the other side.

Lisinopril/Hydrochlorothiazide 20 mg/12.5 mg Tablets are white, round, biconvex tablets debossed with "LH2" over "M" on one side of the tablet and a score line on the other side. The score line is for ease of swallowing and not to divide the tablet into equal halves.

Lisinopril/Hydrochlorothiazide is available in blister packs of 10, 14, 28, 30, 50, 56, 84, 90, 100 tablets, in unit dose blister pack of 100 x 1 tablets and HDPE bottles containing 500 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

McDermott Laboratories Ltd. T/A Gerard Laboratories.
35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13
Ireland

Manufacturer

Mylan Hungary Kft.
Mylan utca1., Komárom, 2900
Hungary

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria: Lisinopril/HCT Arcana 10mg/12.5mg, 20mg/12.5mg Tabletten

Belgium: Co-Lisinomyl 20 mg/12.5 mg tabletten
Germany: Lisinopril/HCT Mylan 10mg/12.5 mg, 20 mg/12.5 mg Tabletten
Denmark: Lisinopril/Hydroklortiazid Mylan
Ireland: Lisinopril/Hydrochlorothiazide 10mg/12.5mg, 20mg/12.5mg Tablets
Luxembourg: Co-Lisinomyl 20 mg/12.5 mg comprimés
Malta: Co-Lisinomyl 10mg/12.5 mg, 20mg/12.5mg Tablets
Netherlands: Lisinopril/Hydrochlorothiazide Mylan 10/12,5 mg, 20/12.5mg tabletten
Portugal: Lisinopril + Hidroclorotiazida Anova
United Kingdom: Lisinopril/Hydrochlorothiazide 10 mg/12.5 mg, 20 mg/12.5 mg Tablets

This leaflet was revised in 03/2017.