

Package leaflet: Information for the patient

Lisigen 5 mg Tablets Lisigen 20 mg Tablets

lisinopril

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. See section 4.

What is in this leaflet

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

1. What Lisigen is and what it is used for

Lisigen contains lisinopril, which 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.

Lisigen can be used for the following conditions:

- to treat high blood pressure (hypertension)
- to treat heart failure
- if you have recently had a heart attack (myocardial infarction)
- to treat kidney problems in diabetic patients with high blood pressure

2. What you need to know before you take Lisigen

Do not take Lisigen:

- if you are allergic to lisinopril, any other angiotensin converting enzyme (ACE) inhibitor e.g. captopril, enalapril, ramipril or any of the other ingredients of this medicine (listed in Section 6).
- if you have ever had a severe allergic reaction to another ACE inhibitor. The allergic reaction may have caused skin rashes, itchy skin and swelling of the hands, ankles face, lips, tongue or throat. It may also have made it difficult to swallow or breathe (angioedema).
- if a family member has ever had a severe allergic reaction (hereditary angioedema) or if you have previously had a severe allergic reaction of an unknown cause (idiopathic angioedema).
- if you are more than 3 months pregnant (it is also better to avoid lisinopril in early pregnancy - see Pregnancy and breast-feeding section).
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.

Do not take Lisigen if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking this medicine.

Warnings and precautions

Talk to your doctor or pharmacist before taking Lisigen

- if you have low blood pressure (hypotension). You may notice this as feeling dizzy or light-headed, especially when standing up. An additional lowering of blood pressure can occur in some patients with heart failure being treated with lisinopril.
- if you are dehydrated due to treatment with diuretic medicine, dialysis, dietary restriction of salt, vomiting or diarrhoea. You may be more likely to suffer from a very large drop in blood pressure when you start taking the tablets and may feel faint or light headed.
- if you suffer from abnormal functioning of the heart, heart failure or heart valve disease, narrowing (stenosis) or hardening of the arteries of your heart or an enlarged heart (known as hypertrophic cardiomyopathy).
- if you have had a stroke or mini-stroke (also known as transient ischaemic attack (TIA))
- if you suffer from kidney disease, improper functioning of the kidneys or narrowing (stenosis) of the blood vessels to the kidney as your dosage may need to be adjusted.
- if you are having kidney dialysis treatment or have had a kidney transplant.
- if you are of black origin as lisinopril may not work as well and you may be more at risk of angioedema (a severe allergic reaction).
- if you need blood separation treatment (apheresis) e.g. for high cholesterol levels or desensitisation treatment e.g. following a wasp or bee sting; your doctor may wish to interrupt your lisinopril treatment to prevent a possible allergic reaction.
- if you have liver problems.
- if you suffer from a collagen vascular disease e.g. scleroderma, SLE or lupus (an allergic condition causing joint pain, skin rashes and fever). Your doctor may perform frequent blood tests to check for any infections that may develop during treatment.
- if you are diabetic.
- if you have high levels of potassium in your blood (hyperkalaemia).
- 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 Lisigen"

- 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)

You must tell your doctor if you think you are (or might become) pregnant. Lisinopril 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 and breast-feeding section).

During treatment

Talk to your doctor or hospital staff if:

- you need to have surgery (including dental surgery) or need anaesthesia. This is because you can get low blood pressure (hypotension) if you are given certain local or general anaesthetics while you are taking this medicine.
- you develop a dry cough which is persistent for a long time after starting treatment with lisinopril.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Lisigen.

Children and adolescents

Lisinopril has only been studied in children with high blood pressure (see section 3, How to take Lisigen). For more information, talk to your doctor. Lisinopril is not recommended in children under 6 years of age or in any child with severe kidney problems.

Other medicines and Lisigen

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

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

- diuretics ('water tablets') e.g. amiloride, triamterene, spironolactone.
- medicines that increase the amount of potassium in your blood. These include potassium supplements or potassium containing salt substitutes, heparin and co-trimoxazole also known as trimethoprim/sulfamethoxazole.
- lithium used to treat certain mental illnesses.
- pain killers called non-steroidal anti-inflammatory drugs (NSAIDs) used to treat pain and inflammation (such as indomethacin, acetylsalicylic acid (when taking more than 3g per day), celecoxib, rofecoxib).
- medicines containing gold e.g. sodium aurothiomalate, which may be given to you by injection for conditions such as arthritis.
- other medicines to help lower your blood pressure (e.g. glyceryl trinitrate).
- medicines to break up blood clots (usually given in hospitals).
- medicines used to stimulate the central nervous system e.g. ephedrine or pseudoephedrine, often found in cough or cold remedies.
- insulin or other medicines for diabetes taken by mouth e.g. gliclazide, metformin; your blood glucose should be monitored closely in the first month of starting lisinopril.
- medicines used to treat depression e.g. amitriptyline
- antipsychotic medicines
- anaesthetic medicines such as lidocaine.
- 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".
- allopurinol (for gout).
- procainamide (to treat abnormal heart rhythms).

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 Lisigen" and "Warnings and precautions").

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking Lisigen before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of this medicine. Lisinopril 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 it is used after the third month of pregnancy.

Breast-feeding

Tell your doctor if you are breast-feeding or about to start breast-feeding. Lisinopril 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

- Some people feel dizzy or tired when taking this medicine. 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.

3. How to take Lisigen

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

At the start of treatment your doctor may monitor your condition closely, take blood tests, check how your kidneys are working and monitor the level of salts in your blood from time to time.

Adults (including the Elderly)

Your dose depends on your medical condition and whether you are taking any other medicines. Your doctor will tell you how many tablets to take each day. Check with your doctor or pharmacist if you are unsure.

To treat high blood pressure: The recommended starting dose is 10 mg daily although, in some cases, this can be lower. Your doctor will slowly increase this to a dose which best controls your blood pressure. The recommended maintenance dose is 20 mg once daily. The maximum dose is 80 mg once daily.

If you are already taking a 'water' tablet (diuretic) for your blood pressure, your doctor may ask you to stop taking your diuretic or to reduce the dose before starting lisinopril. Your doctor may restart the water tablets once your blood pressure is stable.

To treat heart failure: The recommended starting dose is 2.5 mg daily. Based on your response to the treatment your doctor may slowly increase this dose by no more than 10 mg every two weeks or more. The maximum dose is 35 mg once daily. Your doctor may also ask you to take other medicine for your heart problems such as a diuretic, digoxin or a beta-blocker e.g. atenolol.

To treat patients who have suffered a heart attack: The recommended starting dose is 5 mg within 24 hours of your attack and 5 mg one day later. The usual long-term dose is 10 mg once a day. If you have low blood pressure a lower dose of 2.5 mg daily may be given. You should take this medicine for at least 6 weeks.

For kidney problems caused by diabetes: The recommended dose is 10 mg daily. If needed, your doctor will increase this to 20 mg once daily.

Patients with kidney problems may be given a lower dose of lisinopril. Your doctor may adjust to a dose which best controls your blood pressure or to a maximum of 40 mg daily.

Lisinopril is not recommended in patients who have recently had a kidney transplant.

Use in children and adolescents (6 to 16 years old) with high blood pressure

- Lisinopril is not recommended for children under 6 years or in any children with severe kidney problems.
- The doctor will work out the correct dose for your child. The dose depends on the child's body weight.
- For children who weigh between 20 kg and 50 kg, the recommended starting dose is 2.5 mg once a day.

- For children who weigh more than 50 kg, the recommended starting dose is 5 mg once a day.

Taking your medicine

- Swallow the tablets with a glass of water.
- Try to take the tablets at the same time every day. It does not matter if you take Lisigen before or after food.
- Keep taking Lisigen for as long as your doctor tells you to, it is a long term treatment. It is important to keep taking this medicine every day.
- The tablet can be divided into two equal doses.

Taking your first dose

- Take special care when you take your first dose of lisinopril or if your dose is increased. It may cause a greater fall in blood pressure than later doses, especially in patients with severely high blood pressure.
- 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.

If you take more Lisigen than you should

Contact your doctor or nearest hospital emergency department **immediately**. Take the container and any remaining tablets with you. Symptoms of overdose include low blood pressure, shock (a dangerous decrease in blood pressure which, if untreated, may lead to collapse or loss of consciousness), kidney failure, changes in blood salts which may be seen in blood tests, difficulty breathing, increased or decreased heart beat, dizziness, anxiety and cough.

If you forget to take Lisigen

Take the next dose as soon as you remember unless it is almost time for your next dose. **Do not** take a double dose to make up for a forgotten dose.

If you stop taking Lisigen

Do not suddenly stop taking your medicine. If you want to stop the treatment discuss this with your doctor or pharmacist first.

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

4. Possible side effects

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

If any of the following happen, stop taking lisinopril and tell your doctor immediately or go to your nearest hospital emergency department:

Uncommon (may affect up to 1 in 100 people):

- severe sudden chest pain which may spread to the neck, shoulders and arms with shortness of breath and a clammy feeling (these may be signs of a heart attack) or weakness or numbness down one side of the body, confusion, difficulty speaking or loss of coordination (these may be signs of a stroke). These may occur due to a large drop in blood pressure especially if you have symptoms such as severe dizziness, light-headedness at the start of the treatment, when the dose has increased or when you stand up.

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

- severe allergic reactions causing swelling of the hands, face, lips, tongue and/or throat which may cause difficulty breathing or swallowing (angioedema, more likely in black patients) or shortness of breath and wheezing (anaphylaxis). producing little or no urine, cloudy urine or blood in the urine with lower back pain, feeling or being sick (nausea or vomiting) or swelling in your legs, ankles or feet. These may be signs of kidney failure.

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

- severe abdominal pain radiating to the back with being sick (vomiting) or feeling sick (nausea). These may be signs of pancreatitis.
- severe skin reaction which can cause blistering and peeling of the skin, mouth, eyes and genitals. These may be signs of pemphigus, Stevens-Johnson syndrome or if widespread, toxic epidermal necrolysis).
- yellowing of your skin or whites of the eyes (jaundice), dark urine, pale stools, tiredness, fever, feeling sick (nausea), stomach pain and weakness. These may be signs of serious liver problems such as inflammation of the liver or blockage in the bile duct, which can lead to liver failure.
- an increase in the number of infections you may get resulting in fever, severe chills, sore throat or mouth ulcers (these may be signs of a low number of white blood cells in the body and is more likely in patients with kidney problems and a collagen vascular disease e.g. scleroderma, or those on immunosuppressant treatment, allopurinol or procainamide), or if you notice that you bruise or bleed more easily or without explanation, or yellowing of the skin or eyes or feel tired, pale or weak. These may be signs of changes, some serious, in the number or type of blood cells, which may be due to a reduction in the activity of bone marrow (where blood cells are produced).

Other possible side effects include:

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

- dizziness.
- headache.
- cough.
- diarrhoea.
- being sick (vomiting).
- other kidney problems.

Uncommon (may affect up to 1 in 100 people):

- mood changes.
- tingling, pins and needles in the hands or feet.
- feeling of spinning or dizziness when standing still (vertigo).
- taste changes.
- problems sleeping.
- seeing, feeling or hearing things that are not there (hallucinations).
- fast heart beat that may feel like a thumping in your chest (palpitations).
- blood circulation problem causing pale, discoloured, cold, painful fingers or toes.
- an itchy, runny nose.
- skin rash, itchy skin.
- feeling sick (nausea).
- stomach pain and indigestion.
- inability to get or maintain an erection (impotence).
- tiredness.
- weakness.
- raised blood levels of potassium, urea, liver enzymes and creatinine which can be seen in a blood test.

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

- confusion.
- dry mouth.
- a nettle-like rash, hives.
- hair loss.
- skin disease with thickened patches of red skin, often with silvery scales (psoriasis).

- changes in the way things smell.
- high urea levels, which could lead to gout (a painful inflammation of the joints)
- breast enlargement in men.
- a decrease in the haemoglobin levels (blood cells which carry oxygen around) or an increase in bilirubin in the blood which all may be seen in a blood test.
- a lower than normal level of sodium in the blood, which may make you feel tired, weak and confused with aching or twitching muscles, fluid retention fits or loss of consciousness. This may be due to inappropriate ADH secretion, a hormone that causes the body to retain water and dilute the blood, reducing the amount of sodium.

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

- benign (not cancerous) lumps on the skin.
- swollen or enlarged glands in the neck, armpit or groin.
- low sugar (glucose) levels in the blood which can be seen in a blood test and may include symptoms such as sweating, weakness, hunger, dizziness, trembling, headache, flushing or paleness, numbness, having a fast pounding heart beat.
- redness of the skin or target like spots with a dark centre and lighter outer ring.
- wheezing or difficulty breathing due to spasm of the wind pipe
- inflamed and swollen sinuses causing pain, high temperature, tenderness.
- swollen intestines (gut).
- sweating.
- fever, chills, shortness of breath, coughing which produces phlegm or occasionally blood. These may be signs of a serious lung infection (eosinophilic pneumonia) or inflammation (alveolitis).
- a disease where your immune system (which defends your body against diseases) does not recognise healthy cells and attacks them. This is called an autoimmune disease and can affect any part of the body.

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

- signs of depression.
- fainting

One or more of the following have also been seen in patients taking lisinopril: fever, inflamed veins (vasculitis), muscle pain, inflamed or painful joints, rash or other skin problems such as sensitivity to sunlight or blood tests that suggest an increase in white blood cells or inflammation.

Side effects in children

Side effects in children with high blood pressure appear to be comparable to those seen in adults.

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.

You can also report side effects directly via [to be completed nationally]. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Lisigen

- 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.
- This medicinal product does not require any special storage conditions.

Do not throw away 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 Lisigen contains

The active substance is lisinopril dihydrate. The other ingredients are: calcium hydrogen phosphate dihydrate, mannitol, pregelatinised maize starch, croscarmellose sodium, povidone, magnesium stearate/sodium laurilsulfate (94/6), colloidal anhydrous silica and iron oxide red (E172).

Lisigen is supplied in two strengths containing 5 mg or 20 mg of lisinopril (as dihydrate).

What Lisigen looks like and contents of the pack

5 mg: A light pink coloured, mottled, round, biconvex tablet debossed with “L and 23” on either side of the breakline on one side and M on the other side.

20 mg: A pink coloured, mottled, round, biconvex tablet debossed with “M over L 25” on one side of the tablet and breakline on the other side.

Lisigen is packed in blisters in packs of 14 tablets.

Marketing Authorisation Holder

[To be completed nationally]

Manufacturer

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

Mylan Hungary Kft.
Mylan utca1, Komárom, 2900
Hungary

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

Italy: LISINOPRIL MYLAN
Sweden: Lisigen

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[To be completed nationally]