

PACKAGE LEAFLET

Package leaflet: Information for the patient

Zesger 5 mg, 10 mg and 20 mg Tablets lisinopril dihydrate

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

1. What Zesger is and what it is used for

Zesger contains lisinopril, which belongs to a group of medicines called Angiotensin Converting Enzyme (ACE) inhibitors. ACE inhibitors reduce blood pressure and widen blood vessels, this allows the blood to flow more easily and reduces the effort needed to pump blood around the body. Lisinopril is used to treat high blood pressure (hypertension), heart failure, and along with other medicine, may be given following a heart attack. Lisinopril can also be given to treat kidney problems in diabetic patients with high blood pressure (hypertension).

2. What you need to know before you take Zesger

Do not take Zesger:

- 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 previously been treated with an ACE inhibitor and have suffered an allergic reaction. Signs may include swelling of the face, lips, tongue and/or throat with difficulty swallowing or breathing (angioedema).
- if you or a family member have a history of angioedema.
- if you are more than 3 months pregnant. (It is also better to avoid Zesger in early pregnancy – see section ‘Pregnancy and breast-feeding’).
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.

Warnings and precautions

Talk to your doctor or pharmacist before taking Zesger:

- if you have low blood pressure (hypotension)
- 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, hardened arteries, aortic stenosis (narrowing of the heart valve) or an enlarged heart
- 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 of the blood vessels to the kidney, and you have had a kidney removed
- if you are of black origin and taking an ACE inhibitor, you are more at risk of angioedema than a non-black person and this medicine may be less effective.
- if you need dialysis treatment or have had a kidney transplant
- if you need blood separation treatment (apheresis, to help remove cholesterol) 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 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
- 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:
 - a 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 Zesger if”

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 section ‘Pregnancy and breast-feeding’).

During treatment

Talk to your doctor or hospital staff if you need to have surgery or need anaesthesia.

Other medicines and Zesger

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription, or the following:

- diuretics (‘water tablets’) e.g. amiloride, triamterene, spironolactone
- potassium supplements or potassium containing salt substitutes or other drugs which can increase potassium in your body (such as 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 indometacin, aspirin (when taking more than 3g per day), celecoxib, rofecoxib)
- injectable gold, used to treat arthritis e.g. sodium aurothiomalate, which can lead to flushing of the face, nausea, dizziness and low blood pressure
- other medicines to treat high blood pressure e.g. atenolol, glyceryl trinitrate
- medicines to treat depression e.g. amitriptyline
- antipsychotic medicines e.g. fluphenazine
- medicines used to stimulate the central nervous system e.g. ephedrine or pseudoephedrine, often found in cough or cold remedies
- insulin or other antidiabetic medicines e.g. gliclazide, metformin; your blood glucose should be monitored closely in the first month of starting lisinopril
- allopurinol, used to treat gout
- procainamide, used to treat abnormal heart rhythms
- immunosuppressants, used to treat rheumatoid arthritis or after transplant surgery e.g. 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”
- heparin (by injection) or medicines to break up blood clots (usually given in hospitals)
- anaesthetic medicines such as lidocaine.

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 Zesger if” 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 Zesger before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Zesger. 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 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

Do not drive or operate machinery if you feel dizzy or unusually tired while taking this medicine.

3. How to take Zesger

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

- Swallow the tablets with a glass of water
- Try to take the tablets at the same time every day.

At the start of treatment your doctor will monitor your condition closely, take blood tests, check your kidney function and monitor the level of salts in your blood from time to time. This will happen more often if you have kidney problems, a collagen disease or are on allopurinol, probenecid or immunosuppressant treatment.

Adults (including the Elderly) –

To treat high blood pressure: The recommended starting dose is 10 mg daily. In some cases the starting dose is 2.5 mg or 5 mg daily. 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.

Zesger may be less effective in lowering blood pressure in black patients.

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 Zesger. 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 daily. Your doctor may also ask you to take other medicine such as a diuretic and digoxin or a beta-blocker such as atenolol to treat your condition.

To treat patients who have suffered a heart attack: The recommended dose is 5 mg on day 1 and day 2, then 10 mg once daily. If you have low blood pressure your doctor may start the therapy with a lower dose of 2.5 mg daily.

The recommended maintenance dose is 10 mg daily. Your doctor may adjust your dose or even stop the treatment based on your response to the therapy.

To treat conditions relating to 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 Zesger. Your doctor may adjust to a dose which best controls your blood pressure or to a maximum of 40 mg daily.

Treatment with lisinopril is not recommended if you have had kidney transplantation recently.

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

- Zesger 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 to a maximum of 20 mg daily.

- For children who weigh more than 50 kg, the recommended starting dose is 5 mg once a day up to a maximum of 40 mg daily.
- Zesger is not recommended in children in other indications than hypertension.

The tablet can be divided into equal doses.

If you take more Zesger 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, kidney failure, changes in blood salts which may be seen in blood tests, difficulty breathing, increased or decreased heartbeat, dizziness, anxiety and cough.

If you forget to take Zesger

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 tablet.

If you stop taking Zesger

Do not suddenly stop taking your medicine as this may cause serious changes in your blood pressure. If you want to stop the treatment discuss this with your doctor or pharmacist.

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** this medicine and tell your doctor immediately or go to your nearest hospital emergency department:

Uncommon (may affect up to 1 in 100 people)

- severe chest pain which may spread to the neck and shoulders (heart attack) or stroke (especially if you have severe dizziness, light-headedness at the start of treatment or when the dose has increased or when you stand up. These side effects are caused by a large drop in your blood pressure).

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

- feeling unwell, confused and/or weak, feeling sick (nausea), loss of appetite, feeling irritable. This could be something called a syndrome of inappropriate antidiuretic hormone secretion (SIADH).
- kidney failure (with signs such as pain in the back, swelling of the legs, feet, hands and face, tiredness, difficulty passing urine)
- allergic reactions causing swelling of the face, lips, tongue and/or throat which may cause difficulty breathing or swallowing (more likely in black patients), shortness of breath and wheezing

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

- inflammation of the pancreas which may cause severe abdominal pain with sickness
- severe skin reaction which causes blistering of the skin, mouth, eyes and genitals or sores
- severe condition of the skin which causes red, often itchy spots, which start on the limbs and

sometimes on the face and the rest of the body. The spots may blister or may progress to form raised, red, pale-centred marks. Those affected may have fever, joint pain, sore throat, headache and/or diarrhoea

- an increase in infections or fever e.g. sore throat, mouth ulcers that you get (this 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)
- problems with the immune system which may include when the immune system attacks normal body cells.
- yellowing of the skin and whites of the eyes, pale stools, dark coloured urine or stomach pain (these may be signs of liver problems such as inflammation of the liver or blockage in the bile duct), which can lead to liver failure
- lung infection or inflammation of the airways in lungs
- changes in kidney function, passing less urine than usual or no production of urine.

Other possible side effects:

Common (may affect up to 1 in 10 people)

- dizziness, or dizziness on standing up, especially when getting up from a sitting or lying position
- headache
- cough
- diarrhoea
- being sick (vomiting)
- kidney problems

Uncommon (may affect up to 1 in 100 people)

- mood changes
- tingling, pins and needles
- feeling of spinning (vertigo)
- taste changes
- changes in sleeping pattern
- an irregular heart rhythm or missed beats
- faster heart beat
- blood circulation problem causing cold painful fingers
- an itchy runny nose
- feeling sick (nausea)
- stomach pain or discomfort
- hallucinations (seeing, hearing or feeling things that are not there)
- indigestion
- rash or itchy skin
- impotence
- fatigue or weakness
- raised levels of urea, creatinine or liver enzymes in the blood
- raised blood levels of potassium which can cause an abnormal heart rhythm

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

- decrease in blood cells which carry oxygen around the body
- confusion
- changes in sense of smell
- dry mouth
- a nettle-like rash, hives
- hair loss
- skin disease with thickened patches of red skin, often with silvery scales (psoriasis)
- high urea levels, which could lead to gout (a painful inflammation of the joints)
- breast enlargement in men
- increase in bilirubin levels which can cause yellowing of the skin
- low blood levels of sodium which can cause tiredness and confusion, muscle twitching, fits or coma

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

- swollen glands in the neck, armpit or groin
- low sugar (glucose) levels in the blood which can cause sweating, weakness, hunger, dizziness, trembling, headache, flushing or paleness, numbness, having a fast pounding heart beat
- wheezing, difficulty breathing
- inflamed and swollen sinuses causing pain, high temperature, tenderness
- swollen intestines (gut)
- sweating
- disorders of the lymph glands

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

- feeling of depression
- fainting
- changes in the blood (as seen in blood tests) such as an increase in white blood cells.

It is also possible that lisinopril may cause a syndrome of fever, inflammation of vessels, often with skin rash, muscle or bone pain, joint disorder and sensitivity of the skin to light.

Side effects in children

Side effects in children 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 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 Zesger

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 medicine 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 Zesger contains

The active substance is lisinopril. Each tablet contains either 5 mg, 10 mg or 20 mg of lisinopril (as lisinopril dihydrate).

The other ingredients are magnesium stearate, talc, mannitol, maize starch and calcium hydrogen phosphate dihydrate.

What Zesger looks like and contents of the pack

Your medicine comes as a white tablet.

The 5 mg tablets are marked '5' on one side with a breakline on the other. The 10 mg tablets are marked '10' on one side with a breakline on the other. The 20 mg tablets are marked '20' on one side with a breakline on the other.

Zesger 5mg Tablets are available in blisters of 14, 15, 28, 30, 50, 60 and 100 tablets.

Zesger 10 mg Tablets are available in blisters of 15, 28, 30, 50 and 100 tablets.

Zesger 20 mg Tablets are available in blisters of 14, 15, 28, 30, 50 and 100 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

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

Austria - Lisinopril "Arcana" 5mg, 10mg & 20mg Tabletten

Denmark - Lisinopril Mylan 2.5mg, 5mg, 10mg & 20mg tabletter

Belgium - Lisinopril Mylan 5mg & 20mg tabletten

Finland - Lisinopril Mylan 10mg & 20mg Tabletti

Germany - Lisodura 5mg, 10mg & 20mg

Ireland - Zesger 5mg, 10mg & 20mg Tablets

Italy - Lisinopril Mylan Generics 5mg & 20mg compresse

Luxembourg – Lisinopril Mylan CPR. 5mg & 20mg

Sweden - Lisinopril Mylan tablett 2.5 mg, 5mg, 10mg & 20mg

United Kingdom - Lisinopril 2.5 mg, 5mg, 10mg & 20mg Tablets

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