

PACKAGE LEAFLET: INFORMATION FOR THE USER

Zesger 2.5 mg, 5 mg, 10 mg and 20 mg Tablets (lisinopril)

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. What Zesger is and what it is used for
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1. WHAT ZESGER IS AND WHAT IT IS USED FOR

Zesger 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. Zesger Tablets are used to treat high blood pressure (hypertension), heart failure, and along with other medicine, may be given following a heart attack. Zesger can also be given to diabetic patients, to help treat conditions related to their diabetes such as hypertension and kidney problems.

2. BEFORE YOU TAKE ZESGER

Do not take Zesger if

- you are allergic (hypersensitive) to Lisinopril or any of the other ingredients of this medicine.
- you are allergic (hypersensitive) to any other ACE inhibitor eg. Captopril, Enalapril, Ramipril.
- you, or a family member, have previously been treated with an ACE inhibitor and have suffered an allergic reaction. Symptoms may include swelling of the face, lips, tongue and/or throat with difficulty swallowing or breathing (angioedema).
- you are more than 3 months pregnant. (It is also better to avoid Zesger in early pregnancy – see section ‘Pregnancy and breast-feeding’.)

Take special care with Zesger

You should tell your doctor before taking this medicine if you:

- have low blood pressure (hypotension)
- 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.
- suffer from heart valve disease, hardened arteries, aortic stenosis (narrowing of the heart valve) or an enlarged heart

- suffer from kidney disease or narrowing of the blood vessels to the kidney, and you have had a kidney removed
- have previously suffered a serious allergic reaction which causes swelling of the face, lips, tongue and/or throat which causes difficulty breathing or swallowing (angioedema)
- if you are of black origin and taking an ACE inhibitor, you are more at risk of angioedema than a non-black person.
- need dialysis treatment or have had a kidney transplant
- if you need blood separation treatment (apheresis) or desensitisation treatment eg. following a wasp or bee sting; your doctor may wish to interrupt your Zesger treatment to prevent a possible allergic reaction
- suffer from a collagen vascular disease eg. scleroderma, SLE (or lupus, an allergic condition causing joint pain, skin rashes and fever)
- need to have surgery or a general anaesthetic
- are diabetic
- have high levels of potassium in your blood
- You must tell your doctor if you think you are (or might become) pregnant. Zesger 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’).

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, or the following:

- diuretics (‘water tablets’) eg. Amiloride, Triamterene, Spironolactone
- potassium supplements or potassium containing salt substitutes
- lithium used to treat certain mental illnesses
- pain killers called non-steroidal anti-inflammatory drugs (NSAIDs) used to treat pain and inflammation eg. Indometacin, Aspirin
- injectable gold, used to treat arthritis eg. sodium aurothiomalate, which can lead to flushing of the face, nausea, vomiting and low blood pressure
- other medicines to treat high blood pressure eg. atenolol, glyceryl trinitrate
- medicines to treat depression eg. amitriptyline
- antipsychotic medicines eg. fluphenazine
- medicines used to stimulate the central nervous system eg. ephedrine or pseudoephedrine, often found in cough or cold remedies
- insulin or other antidiabetic medicines eg. gliclazide, metformin; your blood glucose should be monitored closely in the first month of starting Zesger
- allopurinol, used to treat gout
- procainamide, used to treat abnormal heart rhythms
- immunosuppressants, used to treat rheumatoid arthritis or after transplant surgery eg. ciclosporin
- heparin (by injection) to treat blood clots
- anaesthetic medicines.

Pregnancy and breast-feeding

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. Zesger 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. Zesger is not recommended for mothers who are breastfeeding, 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.

Ask your doctor or pharmacist for advice before taking any medicine.

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 Zesger exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- Swallow the tablets/capsules 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 usual 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 usual 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. He/she will restart the diuretic once your blood pressure is stable.

To treat heart failure: The usual starting dose is 2.5 mg daily. Your doctor will slowly increase this dose by no more than 10 mg every two weeks or more. The maximum dose is 35 mg daily. You will also be taking other medicine to treat your condition, such as a diuretic and Digoxin or a beta-blocker eg. Atenolol.

To treat patients who have suffered a heart attack: The usual dose is 5 mg on day 1 and day 2, then 10mg once daily. If you have low blood pressure or kidney problems, a lower dose of 2.5 mg daily may be given.

To treat conditions relating to diabetes: The usual 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.

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 20kg and 50 kg, the usual starting dose is 2.5mg once a day to a maximum of 20kg daily.
- For children who weigh more than 50kg, the usual starting dose is 5mg once a day up to a maximum of 40mg daily.
- Zesger is not recommended in children in other indications than hypertension.

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, kidney failure, difficulty breathing, an irregular heart rhythm or missed beats, dizziness, anxiety and a 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 dose.

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, Zesger can cause side effects, although not everybody gets them.

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

- allergic reactions causing swelling of the face, lips, tongue and/or throat which may cause difficulty breathing or swallowing (more likely in black patients), or very rarely, shortness of breath and wheezing (Uncommon)
- abdominal pain with sickness (Very rare)
- severe skin reaction which causes blistering of the skin, mouth, eyes and genitals or sores (Very rare)
- 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, sore throat, headache and/or diarrhoea. (Very rare)
- severe chest pain which may spread to the neck and shoulders (Uncommon)
- yellowing of your skin or whites of the eyes, which can lead to liver failure.(Very rare).

It is very important that you stop taking Zesger immediately and see your doctor if you have severe dizziness, light-headedness (especially 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 and could lead to a

heart attack (severe chest pain) or stroke.

Common side effects (affecting fewer than 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 side effects (affecting fewer than 1 in 100 people):

- mood changes
- tingling, pins and needles
- feeling of spinning, dizziness (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
- 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 side effects (affecting fewer than 1 in 1,000 people):

- decrease in blood cells which carry oxygen around the body
- confusion
- 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)
- kidney disease
- 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
- 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).

Very rare side effects (affecting fewer than 1 in 10,000 people):

- reduction in red or white blood cells or platelets which can cause weakness or breathlessness, tiredness, headaches, dizziness, looking pale and yellowing of the skin and/or eyes
- reduction in blood platelets which increases the risk of bleeding or bruising
- reduction in white blood cells which can increase infections such as fever, severe chills, sore throat or

mouth ulcers. This is more likely in patients with kidney problems and a collagen vascular disease eg. scleroderma, or those on immunosuppressant treatment, allopurinol or procainamide.

- swollen glands in the neck, armpit or groin
- problems with the immune system
- 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
- lung infection
- inflammation of the pancreas which causes severe pain in the abdomen and back
- swollen intestines (gut)
- a liver disease which can cause nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, light coloured bowel motions, dark coloured urine
- sweating
- disorders of the lymph glands
- changes in urine function, passing more urine than usual or no production of urine.

It is also possible that Zesger may cause: fainting, feelings of depression, fever, inflammation of vessels, often with skin rash, joint pain and sensitivity of the skin to light.

Side effects in children appear to be comparable to those seen in adults.

If any side effect gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE ZESGER

Keep out of the reach and sight of children.

Do not use Zesger 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.

There are no special precautions for storage of this medicine.

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.

6. FURTHER INFORMATION

What Zesger contains

The active substance is Lisinopril. Each tablet contains 2.5 mg, 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 2.5 mg tablets are marked '2.5' on one side with a breakline on the other. 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 2.5 mg Tablets are available in blisters of 14, 28, 30, 50 and 100 tablets.

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 5mg, 10mg & 20mg Tabletti

Germany - Lisodura 5mg, 10mg & 20mg

Ireland - Zesger 2.5mg, 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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