

Package leaflet: Information for the patient

Zesger Plus 20mg/12.5mg 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 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 Plus is and what it is used for
2. What you need to know before you take Zesger Plus
3. How to take Zesger Plus
4. Possible side effects
5. How to store Zesger Plus
6. Contents of the pack and other information

1. What Zesger Plus is and what it is used for

Zesger Plus contains the active substances, lisinopril, which belongs to a group of medicines known as ACE (angiotensin converting enzyme) inhibitors and hydrochlorothiazide, which belongs to a group of medicines known as thiazide diuretics, which work together to lower your blood pressure. You have been given Zesger Plus because your high blood pressure was not being adequately treated using lisinopril or hydrochlorothiazide alone.

2. What you need to know before you take Zesger Plus

Do not take Zesger Plus

- if you are allergic to lisinopril, hydrochlorothiazide or any of the other ingredients of this medicine (listed in section 6)
- if you are allergic to other ACE inhibitors or other sulfonamides (medicines chemically related to hydrochlorothiazide such as some antibiotics)
- if you have previously been treated with an ACE inhibitor and have suffered an allergic reaction called angioedema. Symptoms may include swelling of the face, lips, tongue or hands and feet, or breathing difficulties
- if you or one of your family have ever suffered from the allergic reaction called angioedema for any reason
- if you have severe kidney disease or cannot pass urine
- if you are more than 3 months pregnant (it is also better to avoid Zesger Plus in early pregnancy – see Pregnancy section)
- if you have severe liver disease
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.
- if you have taken or are currently taking sacubitril/valsartan, a medicine used to treat a type of long-term (chronic) heart failure in adults, as the risk of angioedema (rapid swelling under the skin in an area such as the throat) is increased.

Ask your doctor if you are not sure.

Warnings and precautions

Talk to your doctor or pharmacist before taking Zesger Plus:

- if you feel dehydrated due to treatment with diuretics (water tablets), dialysis, a low salt diet, vomiting or diarrhoea. You may be more likely to suffer from a large drop in your blood pressure when you start taking your tablets and may feel faint or light-headed. Your doctor will monitor you closely at the start of treatment and if your dose is adjusted
- if you think you are (or might become) pregnant. Zesger Plus Tablets are 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)
- if you have had skin cancer or if you develop an unexpected skin lesion during the treatment. Treatment with hydrochlorothiazide, particularly long-term use with high doses, may increase the risk of some types of skin and lip cancer (non-melanoma skin cancer). Protect your skin from sun exposure and UV rays while taking Zesger Plus
- if you are at risk of high levels of potassium in your blood e.g. from taking potassium-containing salt substitutes or supplements
- if you have heart or blood vessel disease (e.g. angina) or problems with blood supply to the brain
- if you have an enlarged heart
- if you have a narrowing (stenosis) of the aorta (an artery in your heart) or mitral valve (a valve in your heart)
- if you are suffering from heart failure
- if you have other liver problems
- if you have other kidney problems, need dialysis treatment or have had a kidney transplant
- if you suffer from narrowing of the blood vessels to one or both kidneys
- if you have diabetes. As you may need a different dose of your antidiabetic medicine (including insulin)
- if you suffer from gout or increased uric acid levels in your blood
- if you suffer from increased levels of cholesterol or blood fats
- if you have a history of allergy, bronchial asthma or a collagen vascular disease e.g. scleroderma, SLE (system lupus erythematosus is an allergic condition causing joint pain, rashes and fever)
- 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 treatment with this medicine to prevent a possible allergic reaction
- 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) maybe increased:
 - racecadotril (a medicine used to treat diarrhoea)
 - medicines used to prevent organ transplant rejection and for cancer (e.g. temsirolimus, sirolimus, everolimus)
 - vildagliptin (a medicine used to treat diabetes).

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 Plus'

Use in Afro-Caribbean patients: ACE inhibitors 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).

While taking Zesger Plus

If you develop any of the following symptoms let your doctor know immediately:

- If you feel dizzy after your first dose. A few people react to their first dose or when the dose is increased by feeling dizzy, weak, faint and sick. Lie down if your blood pressure drops too low.
- Complaints such as a dry mouth, thirst, weakness, lethargy, muscle weakness, pain or cramps, a racing heart, dizziness, feeling or being sick, and passing less urine, are signs of a fluid or mineral imbalance in the body.
- Sudden swelling of the lips, face, neck, and possibly hands and feet, a rash, difficulty swallowing or breathing, hoarseness, are signs of angioedema. This may occur at any time during treatment. There is a higher risk in Afro-Caribbean patients.
- High temperature, sore throat and mouth ulcers, are signs of a low white cell count in the blood
- Yellowing of the skin or whites of the eyes, which may be a sign of liver problems.

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.

If you need surgery or any blood tests:

Tell the doctor, nurse, dentist or hospital staff that you are taking this medicine if:

- you are undergoing tests to check your parathyroid function, as this medicine may alter your test results.
- you need to have surgery or a general anaesthetic
- you play competitive sports, as hydrochlorothiazide is a banned substance and may give a positive result in anti-doping tests

Other medicines and Zesger Plus

You should not take Zesger Plus if you have taken or are currently taking sacubitril/valsartan (see 'Do not take Zesger Plus' above).

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

- other diuretic ('water' tablets)
- other medicines to treat high blood pressure e.g. a beta blocker such as sotalol, or a nitrate (which may also be used for chest pain e.g. angina)
- medicines known as cardiac glycosides (e.g. digoxin used for a heart condition)
- potassium supplements (including salt substitutes), potassium-sparing diuretics and other medicines that can increase the amount of potassium in your blood (e.g. trimethoprim and co-trimoxazole for infections caused by bacteria; ciclosporin, an immunosuppressant medicine used to prevent organ transplant rejection; and heparin, a medicine used to thin blood to prevent clots)
- medicines known to cause a serious type of heart rhythm disorder called torsades de pointes (e.g. certain medicines used to treat heart rhythm disorders or mental illness), this is more likely if potassium levels in the body are low
- treatment with Tissue plasminogen activators (tPA's), medicines used to treat blood clots (usually given in hospitals)
- medicine containing calcium salts or vitamin D supplements
- anti-inflammatory medicine called NSAIDs e.g. ibuprofen or COX-2 inhibitors e.g. celecoxib (to treat arthritis or muscle pain)
- aspirin (in doses used to treat heart disorders)
- lithium (medicine for depression)
- anaesthetics (e.g. lidocaine, bupivacaine) and medicines for mental disorders or depression, to treat psychoses (e.g. haloperidol, chlorpromazine), tricyclic antidepressants (e.g. amitriptyline, clomipramine, imipramine), or sedatives (e.g. lorazepam, alprazolam)
- antidiabetic medicine e.g. insulin, gliclazide; your blood glucose should be monitored closely in the first few weeks of treatment
- allopurinol (for gout)

- medicines used to prevent organ transplant rejection and for cancer (e.g. temsirolimus, sirolimus, everolimus). See section ‘Warnings and precautions’.
- racecadotril (used to treat diarrhoea)
- vildagliptin (to treat diabetes)
- anti-cancer medicines
- colestyramine, colestipol, (help reduce blood fat levels); take Zesger Plus dose at least one hour before or four to six hours after these medicines
- lovastatin (helps reduce cholesterol)
- procainamide (for an irregular heart rhythm)
- carbenoxolone (for throat ulcers)
- corticosteroids (such as hydrocortisone used as anti-inflammatory medicines)
- corticotropin (for rheumatoid arthritis or Crohn’s disease)
- laxatives such as senna
- amphotericin B by injection (for fungal infections)
- trimethoprim (antibiotic)
- amantadine (used as an antiviral or to treat Parkinson’s disease)
- medicines used to stimulate the central nervous system e.g. ephedrine or pseudoephedrine, often found in cough and cold remedies
- muscle relaxants such as tubocurarine
- medicines that contain gold, such as sodium aurothiomalate, which may be given to you as an injection

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 Plus’ and ‘Warnings and precautions’).

Zesger Plus with alcohol

You should not drink alcohol while being treated with this medicine, because it will further worsen your ability to drive and use machines.

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

Breast-feeding

Tell your doctor if you are breast-feeding or about to start breast-feeding. Zesger Plus 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 can sometimes make people feel faint or dizzy. This may especially be the case at the start of treatment or when changing the dose. If you are affected, you **should not** drive a car or operate machinery. Occasionally, dizziness or tiredness may occur when driving vehicles or operating machinery. These side effects may be worse if you drink alcohol at the same time.

3. How to take Zesger Plus

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

The recommended dose is:

Adults (including elderly)

The starting dose is one tablet daily. Your doctor will decide which strength of tablet to start you on. The maximum daily dose is two 20 mg/12.5 mg strength tablets once a day.

Patients with kidney problems

If you have kidney problems your doctor will check your kidney function. You may be given a lower dose than stated above. This medicine should not be given to patients with severe kidney problems (see section 2, Do not take Zesger Plus).

Use in children and adolescents (under 18 years)

Zesger Plus **is not recommended** for children and adolescents as the medicine's safety and effectiveness in this age group is not known.

How to take

- Take the tablets with a glass of water.
- Try to take the tablets at the same time each day. Many patients prefer to take Zesger Plus in the morning so that the effects of the diuretic (passing more water than usual) occur during the daytime.
- If you are taking this medicine for the first time or your dose is increased, you may feel light-headed or dizzy for a short time and it may help to sit or lie down. This is unlikely to happen when you are taking the tablets regularly. If you are worried, contact your doctor.

If you take more Zesger Plus than you should

Contact your doctor or nearest hospital emergency department immediately. Take this leaflet, the container and any remaining tablets with you so your doctor will know what you have taken.

Symptoms of overdose may include severe low blood pressure, an unusual amount of salt in the body and dehydration due to passing a large amount of urine, fast breathing, shock, fast or irregular heart beat, slow heartbeat, dizziness, reduced consciousness (which may even lead to coma), impaired movement, fits, anxiety, cough and kidney failure.

If you forget to take Zesger Plus

Take your normal dose when it is next due. Do not take a double dose to make up for a forgotten dose.

If you stop taking Zesger Plus

Do not suddenly stop taking this 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 Zesger Plus and tell your doctor immediately or go to your nearest hospital emergency department:

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

- inflammation of the pancreas, which may cause severe abdominal pain with sickness
- severe chest pain which may spread to the neck and shoulders (heart attack) or stroke. These are more likely to occur if you have severe dizziness, light-headedness etc. when you stand up after taking the medicine at the start of treatment or when the dose has increased and you also have other health problems. Your doctor should monitor you closely to help reduce the risk.

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).
- severe allergic reactions. The signs may include onset of:
 - swelling of the face, lips, tongue and/or throat, hands or feet which may cause difficulty breathing or swallowing
 - Severe itching of the skin (with raised lumps)
- kidney problems or failure (with signs such as pain in the back, swelling of the legs, feet, hands and face, tiredness, difficulty passing urine) which may cause a build-up of urea in the blood (a condition known as uraemia)

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

- lung problems such as infection or inflammation in the lungs caused by allergy
- 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.
- swelling of the lining of the gut. This may cause sudden stomach pain, diarrhoea or make you be sick (vomit)
- yellowing of your skin or whites of the eyes, pale stools, dark 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.
- severe skin reactions such as blistering of the skin, mouth, eyes and genitals or sores which may also include fever, joint or muscle pains, inflamed blood vessels, sensitivity to sunlight, increase in white blood cells (which may be seen in blood tests), immune system disorders.
- 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 SLE, 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, 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.
- changes in kidney function, passing less urine than usual or no production of urine.

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

- skin and lip cancer (non-melanoma skin cancer)
- infection or inflammation of the salivary gland
- irregular heart beat (cardiac arrhythmia)
- increased pressure in your eyes which may cause reduced vision

Other side effects include:

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

- dizziness, which generally goes if the dose is reduced
- light-headedness when standing up quickly, low blood pressure (hypotension)

- headache
- dry and persistent cough; tell your doctor as they may decide to change your medicine
- tiredness
- being sick, diarrhoea
- problems with kidney function
- fainting

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

- a racing or, increased heartbeat or a pounding heart (palpitations)
- chest pain, muscle spasms or weakness
- painful, cold and bluish fingers and toes caused by blood circulation problems
- pins and needles in the limbs, feeling weak or tired
- feeling sick
- indigestion, stomach pain, dry mouth
- taste changes
- mood changes
- sleep problems
- skin rash, itchy skin
- painful, swollen joints (gout)
- impotence
- feeling of spinning (vertigo)
- a runny itchy nose
- increase in potassium levels which if severe can cause an abnormal heart rhythm, muscle weakness or cramps
- depressive symptoms
- raised creatinine levels in the blood (which may indicate kidney problems)
- elevated liver enzyme and bilirubin levels in the blood
- increased blood urea (and/or blood urea nitrogen) levels

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

- mental confusion
- hair loss
- psoriasis, a skin condition, red scaly patches on the skin
- swollen breasts (in men)
- changes in sense of smell
- hives (nettle rash)
- changes to some of the red blood cells of your blood, which may be seen in blood tests
- low levels of sodium (salt) which can make you feel weak and confused with aching, stiff muscles

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

- inflamed and swollen sinuses causing pain, high temperature and tenderness
- sweating
- enlargement of the lymph nodes
- low blood glucose levels which can cause sweating, feeling excessively hungry, trembling, a fast pounding heart beat

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

- flushing
- Seeing hearing or feeling things that are not there (hallucinations)

Other side effects reported with hydrochlorothiazide alone are:

- loss of appetite
- eyesight changes such as blurred vision, yellowing of colour vision, short-sightedness
- fever

- glucose in the urine
- restlessness
- constipation
- inflammation of the blood vessels
- upset stomach
- high calcium levels in blood, low level of chloride, potassium or magnesium in blood
- raised blood glucose levels causing symptoms such as feeling very thirsty and tired, passing large amounts of urine, weight loss
- raised cholesterol or triglyceride (blood fat) levels
- raised blood levels of uric acid (which may be associated with gout)

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 FREE 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 Plus

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 Plus contains

The active substances are:

Each Zesger Plus 20mg/12.5mg Tablet contains 20mg of lisinopril (as the dihydrate) and 12.5mg of hydrochlorothiazide.

The other ingredients are calcium hydrogen phosphate dihydrate, mannitol, maize starch, pregelatinized starch and magnesium stearate. The 20mg/12.5mg strength tablets also contain iron oxide (E172).

What Zesger Plus looks like and contents of the pack

Zesger Plus 20mg/12.5mg Tablets come as pink, round tablets marked LHZ on one side and 32.5 on the other side.

Zesger Plus Tablets are available in blister packs of 10, 14, 28, 30, 50, 56 and 100. Not all pack sizes may be marketed.

Marketing Authorisation Holder

McDermott Laboratories Limited, t/a Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.

Manufacturer

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Laboratories Lesvi SL, Avinguda de Barcelona 69, 08970 Sant Joan Despi, Barcelona, Spain

Generics [UK] Ltd., Station Close, Potters Bar, Herts, EN6 1TL, UK

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

Denmark - LISINOHYD MITE, tablets 10mg/12.5mg & LISINOHYD, tablets 20mg/12.5mg

Austria - Lisinopril "Arcana" comp. 10 mg/12,5 mg & 20 mg/12,5 mg Tabletten

Belgium - Co-Lisinopril Mylan 20/12,5 mg tabletten

Germany - Lisinopril comp. Heumann 10/12.5mg

Greece - Lisinopril+Hydrochlorothiazide/Generics TAB (20+12,5) mg/TAB

Ireland - Zesger Plus 20mg/12.5mg Tablets

Italy – Lisinopril Idrochlorotiazide Mylan Generics 20mg/ 12.5mg Compresse

Luxembourg -Co-Lisinopril Mylan 20mg/12.5mg Tabletten

Portugal - Lisinopril + hidroclorotiazida Mylan Genericos 20 mg + 12,5 mg

Sweden - Lisinopril/Hydroklortiazid Mylan 10mg/12,5mg tablett

The Netherlands - Lisinopril/Hydrochloorthiazide Mylan 20/12,5 mg

UK - Lisinopril and Hydrochlorothiazide 10mg/12.5mg & 20mg/12.5mg Tablets

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