Package leaflet: Information for the patient

Zestril 5 mg Tablets
Zestril 10 mg Tablets
Zestril 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 Zestril is and what it is used for
2. What you need to know before you take Zestril
3. How to take Zestril
4. Possible side effects
5. How to store Zestril
6. Contents of the pack and other information

1. What Zestril is and what it is used for

Zestril contains a medicine called lisinopril. This belongs to a group of medicines called ACE inhibitors.

Zestril 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 caused by Type II diabetes in people with high blood pressure.

Zestril works by making your blood vessels widen. This helps to lower your blood pressure. It also makes it easier for your heart to pump blood to all parts of your body.

2. What you need to know before you take Zestril

Do not take Zestril:
- if you are allergic to lisinopril or any of the other ingredients of this medicine (listed in section 6).
- if you have ever had an allergic reaction to another ACE inhibitor medicine. The allergic reaction may have caused swelling of the hands, feet, ankles, face, lips, tongue or throat. It may also have made it difficult to swallow or breathe (angioedema).
- 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.

- if a member of your family has had severe allergic reactions (angioedema) to an ACE inhibitor or you have had severe allergic reactions (angioedema) without a known cause.
- if you are more than 3 months pregnant. (It is also better to avoid Zestril in early pregnancy - see Pregnancy section).
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.

If you are not sure if any of these apply to you, talk to your doctor or pharmacist before taking Zestril.

If you develop a dry cough which is persistent for a long time after starting treatment with Zestril, talk to your doctor.

Warnings and precautions
Talk to your doctor or pharmacist before taking Zestril:
- if you have a narrowing (stenosis) of the aorta (an artery in your heart) or a narrowing of the heart valves (mitral valves).
- if you have a narrowing (stenosis) of the kidney artery.
- if you have an increase in the thickness of the heart muscle (known as hypertrophic cardiomyopathy).
- 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.
- if you have liver problems.
- if you have diabetes.
- if you are taking any of the following medicines, the risk of angioedema (rapid swelling under the skin in area such as the throat) is increased:
  - temsirolimus, sirolimus, everolimus and other medicines belonging to the class of mTOR inhibitors (used to avoid rejection of transplanted organs and for cancer).
  - Racecadotril, a medicine used to treat diarrhoea;
  - Vildagliptin, a medicine used to treat 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.

  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 Zestril”.
- if you have recently had diarrhoea or vomiting (being sick).
- if your doctor has told you to control the amount of salt in your diet.
- if you have high levels of cholesterol and you are having a treatment called ‘LDL apheresis’.
- you must tell your doctor if you think you are (or might become) pregnant. Zestril 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 section).

- if you are of black origin as Zestril may be less effective. You may also more readily get the side effect 'angioedema' (a severe allergic reaction).

If you are not sure if any of these apply to you, talk to your doctor or pharmacist before taking Zestril.

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 Zestril 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 your doctor or dentist that you are taking Zestril. This is because you can get low blood pressure (hypotension) if you are given certain local or general anaesthetics while you are taking Zestril.

Children and adolescents
Zestril has been studied in children. For more information, talk to your doctor. Zestril is not recommended in children under 6 years of age or in any child with severe kidney problems.

Other medicines and Zestril
Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines. This is because Zestril can affect the way some medicines work and some medicines can have an effect on Zestril. Your doctor may need to change your dose and/or to take other precautions.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:
- Other medicines to help lower your blood pressure.
- An angiotensin II receptor blocker (ARB) or aliskiren, (see also information under the headings "Do not take Zestril" and "Warnings and precautions").
- Water tablets (diuretic medicines).
- Beta-blocker medicines, such as atenolol and propranolol.
- Nitrate medicines (for heart problems).
- Non-steroidal anti-inflammatory drugs (NSAIDs) used to treat pain and arthritis.
- Aspirin (Acetylsalicylic acid), if you are taking more than 3 grams each day.
- Medicines for depression and for mental problems, including lithium.
- 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).
- Insulin or medicines that you take by mouth for diabetes.
- Medicines used to treat asthma.
- Medicines to treat nose or sinus congestion or other cold remedies (including those you can buy in the pharmacy).
- Medicines to suppress the body's immune response (immunosuppressants).
- Allopurinol (for gout).
- Procainamide (for heart beat problems).
- Medicines that contain gold, such as sodium aurothiomalate, which may be given to you as an injection.

The following medicines may increase the risk of angioedema (signs of angioedema include swelling of the face, lips, tongue and/or throat with difficulty in swallowing or breathing):
- Medicines to break up blood clots (tissue plasminogen activator), usually given in hospital.
- Medicines which are most often used to avoid rejection of transplanted organs (temsirolimus, sirolimus, everolimus and other medicines belonging to the class of mTOR inhibitors). See section 2 “Warnings and precautions”.
- Racecadotril used to treat diarrhoea.
- Vildagliptin, a medicine used to treat diabetes.

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

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

Once you have started taking Zestril 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 Zestril before or after food.
- Keep taking Zestril for as long as your doctor tells you to, it is a long term treatment. It is important to keep taking Zestril every day.

Taking your first dose

- Take special care when you have your first dose of Zestril 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
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.

For high blood pressure
- The recommended starting dose is 10 mg once a day.
- The usual long-term dose is 20 mg once a day.

For heart failure
- The recommended starting dose is 2.5 mg once a day.
- The long-term dose is 5 to 35 mg once a day.

After 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.

For kidney problems caused by diabetes
- The recommended dose is either 10 mg or 20 mg once a day.

If you are elderly, have kidney problems or are taking diuretic medicines your doctor may give you a lower dose than the usual dose.

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

If you take more Zestril than you should
If you take more Zestril than prescribed by your doctor, talk to a doctor or go to a hospital immediately. The following effects are most likely to happen: Dizziness, palpitations.

If you forget to take Zestril
- 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 Zestril

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 or pharmacist.

4. Possible side effects

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

If you experience any of the following reactions, **stop taking Zestril and see your doctor immediately:**

- Severe allergic reactions (rare, affects 1 to 10 users in 10,000). The signs may include sudden onset of:
  - Swelling of your face, lips, tongue or throat. This may make it difficult to swallow. This can occur at any time during treatment.
  - Severe or sudden swelling of your hands, feet and ankles.
  - Difficulty breathing.
  - Severe itching of the skin (with raised lumps).
- Severe skin disorders, like a sudden, unexpected rash or burning, red or peeling skin (very rare, affects less than 1 user in 10,000).
- An infection with symptoms such as fever and serious deterioration of your general condition, or fever with local infection symptoms such as sore throat/pharynx/mouth or urinary problems (very rare, affects less than 1 user in 10,000).

Other possible side effects:

Common (affects 1 to 10 users in 100)

- Headache.
- Feeling dizzy or light-headed, especially if you stand up quickly.
- Diarrhoea.
- A dry cough that does not go away.
- Being sick (vomiting).
- Kidney problems (shown in a blood test).

Uncommon (affects 1 to 10 users in 1,000)

- Mood changes.
- Change of colour in your fingers or toes (pale blue followed by redness) or numbness or tingling in your fingers or toes.
- Changes in the way things taste.
- Feeling sleepy.
- Spinning feeling (vertigo).
- Having difficulty sleeping.
- Stroke.
- Fast heart beat.
- Runny nose.
- Feeling sick (nausea).
- Stomach pain or indigestion.
- Skin rash or itching.
- Being unable to get an erection (impotence).
- Feeling tired or feeling weak (loss of strength).

- A very big drop in blood pressure may happen in people with the following conditions: coronary heart disease; narrowing of the aorta (a heart artery), kidney artery or heart valves; an increase in the thickness of the heart muscle. If this happens to you, you may feel dizzy or light-headed, especially if you stand up quickly.
- Changes in blood tests that show how well your liver and kidneys are working.
- Heart attack.
- Seen and/or heard hallucinations.

Rare (affects 1 to 10 users in 10,000)
- Feeling confused.
- A lumpy rash (hives).
- Dry mouth.
- Hair loss.
- Psoriasis (a skin problem).
- Changes in the way things smell.
- Development of breasts in men.
- Changes to some of the cells or other parts of your blood. Your doctor may take blood samples from time to time to check whether Zestril has had any effect on your blood. The signs may include feeling tired, pale skin, a sore throat, high temperature (fever), joint and muscle pains, swelling of the joints or glands, or sensitivity to sunlight.
- Low levels of sodium in your blood (the symptoms may be tiredness, headache, nausea, vomiting).
- Sudden renal failure.

Very rare (affect less than 1 user in 10,000)
- Sinusitis (a feeling of pain and fullness behind your cheeks and eyes).
- Wheezing.
- Low levels of sugar in your blood (hypoglycaemia). The signs may include feeling hungry or weak, sweating and a fast heart beat.
- Inflammation of the lungs. The signs include cough, feeling short of breath and high temperature (fever).
- Yellowing of the skin or the whites of the eyes (jaundice).
- Inflammation of the liver. This can cause loss of appetite, yellowing of the skin and eyes, and dark coloured urine.
- Inflammation of the pancreas. This causes moderate to severe pain in the stomach.
- Severe skin disorders. The symptoms include redness, blistering and peeling.
- Sweating.
- Passing less water (urine) than normal or passing no water.
- Liver failure.
- Lumps.
- Inflamed gut.

Not known (frequency cannot be estimated from available data)
- Symptoms of depression.
- Fainting.

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

5. How to store Zestril

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date (EXP) which is stated on the blister strip and the carton. The expiry date refers to the last day of that month.
- 5 mg, 10 mg and 20 mg tablets: Do not store above 30ºC.
- Do not throw away any medicines via waste-water 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 Zestril contains

- The active substance is lisinopril (as dihydrate).
- The other ingredients are mannitol, calcium hydrogen phosphate dihydrate, maize starch, pregelatinised starch and magnesium stearate. In addition, the pink and brownish-red tablets contain red iron oxide (E172).

Zestril is supplied in 3 strengths containing 5 mg, 10 mg or 20 mg of lisinopril (as dihydrate).

What Zestril looks like and contents of the pack

Zestril 5 mg Tablets: round, pink, uncoated, biconvex tablet with "♥ 5" on one side and bisected on the other side. Diameter 6 mm.
The tablet can be divided into equal doses.
Zestril 10 mg Tablets: round, pink, uncoated, biconvex tablet with "♥ 10" on one side and plain on the other side. Diameter 8 mm.
Zestril 20 mg Tablets: round, brownish-red, uncoated, biconvex tablet with "♥ 20" on one side and plain on the other side. Diameter 8 mm.

Zestril tablets are available in aluminium foil blister packs of 14, 20, 28, 28x1, 30, 42, 50, 56, 56x1, 60, 84, 98, 100, 400 and 500 tablets. Blister packs containing multiples of 7 tablets may also be available with weekday marks.
Zestril tablets are also available in bottle packs of 20, 30, 50, 100 and 400 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

The Marketing Authorisation for Zestril in United Kingdom is held by Atnahs Pharma UK Limited, Sovereign House, Miles Gray Road, Basildon, Essex , SS14 3FR, United Kingdom.

Manufacturer
Zestril is manufactured by AstraZeneca UK Limited, Silk Road Business Park, Macclesfield, Cheshire SK10 2NA, UK.

ROVI Pharma Industrial Services S. A.,Vía Complutense, 140, Alcalá de Henares, Madrid, 28805, Spain.

This medicine is authorised in the Member States of the EEA under the following names: ACEMIN (AT), ZESTRIL (BE, ES, IE, FR, IT, EL, LU, NO, NL, SE, UK), Zestril-5/Zestril Mite/Zestril (PT).

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK only)

Please be ready to give the following information:

Product name	Reference Number
Zestril 5 mg Tablets	PL 43252/0031
Zestril 10 mg Tablets	PL 43252/0032
Zestril 20 mg Tablets	PL 43252/0033

This is a service provided by the Royal National Institute of Blind People.

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