

Lisinopril (5 mg, 10 mg & 20 mg)

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What Zestril 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.

How Zestril works

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.

Before you use Zestril

- When you must not use it

Do not take Zestril:

- if you are allergic (hypersensitive) to lisinopril or any of the other ingredients of Zestril.
- 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 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 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.

- Before you start to use it

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:
 - sirolimus, everolimus and other medicines belonging to the class of mTOR inhibitors (used to avoid rejection of transplanted organs).
- 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 “*When you must not use it*”.

- 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 the above apply to you, talk to your doctor or pharmacist before taking Zestril.

- Taking other medicines

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

“When you must not use it” and “Before you start to use it”).

- 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, salt substitutes that have potassium in them or other drugs that may increase serum potassium in your body (such as heparin, and co-trimoxazole also known as trimethoprim/sulfamethoxazole).
- 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 clot (tissue plasminogen activator), usually given in hospital.
- 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 “Before you start to use it”.
- Racecadotril used to treat diarrhoea.

How to use Zestril

- How much to use

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 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.

- When to use it

- 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.

- How long to use it

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.

- If you forget to use it

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 use too much (overdose)

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.

While you are using it

- Things you must do

Take your medication as advised by your doctor or pharmacist.

- Things you must not do

Do not stop taking the medication unless being told by your doctor or pharmacist.

- Things to be careful of

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 the 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.

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.

Side effects

Like all medicines, Zestril 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.
 - 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.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Zestril

- Storage

Keep out of the reach and sight 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 30°C.

- Disposal

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.

Product Description

- What it looks like

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 28 tablets.

- Ingredients

- Active ingredient(s)

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

- Inactive ingredients

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).

- MAL number:

Zestril 5 mg:
MAL19890679ACZ
Zestril 10 mg:
MAL19890680ACZ
Zestril 20 mg:
MAL19890681ACZ

Manufacturer

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

Product Registration Holder

DKSH Malaysia Sdn. Bhd.
B-11-01, The Ascent, Paradigm,
No. 1, Jalan SS7/26A, Kelana Jaya,

47301 Petaling Jaya,
Selangor, Malaysia.

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