

Package leaflet: Information for the user
Lestace 2.5 mg, 5 mg, 10 mg and 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 Lestace Tablets are and what they are used for
2. What you need to know before you take Lestace Tablets
3. How to take Lestace Tablets
4. Possible side effects
5. How to store Lestace Tablets
6. Contents of the pack and other information

1. What Lestace Tablets is and what it is used for

Lestace Tablets belong to a group of medicines called ACE inhibitors (Angiotensin Converting Enzyme inhibitors). It acts by widening the blood vessels, which helps reduce your blood pressure and makes it easier for the heart to pump blood to all parts of your body.

Lestace Tablets are used for the treatment of:

- High blood pressure (hypertension)
- Symptomatic heart failure, a condition where the heart does not pump the blood through your body as well as it should.
- Heart attack (acute myocardial infarction) that may lead to a weakening of your heart.
- Kidney problems related to Type II diabetes in people with high blood pressure.

Lestace is recommended in children and adolescents (6 to 16 years old) only for the treatment of high blood pressure (hypertension).

2. What you need to know before you take Lestace Tablets

Do not take Lestace Tablets

- if you are allergic to lisinopril or any of the other ingredients of this medicine (listed in section 6) or any other medicine in the same group of drugs as Lestace Tablets (ACE inhibitors)
- if you have previously been treated with a medicine in the same group of drugs as Lestace Tablets (ACE inhibitors) and have had an allergic reaction which caused swelling of the hands, feet or ankles, the face, lips, tongue and/or throat with difficulty in swallowing or breathing (angioedema)
- if you know of severe allergic reactions (angioedema) in your family or you have had angioedema in any other circumstances
- if you are more than 3 months pregnant. (It is also better to avoid Lestace Tablets 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 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.

Warnings and precautions

Talk to your doctor or pharmacist before taking Lestace Tablets:

- if you are dehydrated due to treatment with diuretics (or ‘water tablets’), dialysis, a low salt diet or because you have had diarrhoea or you have been sick. You are more likely to suffer from a drop in your blood pressure (hypotension) when you start to take the tablets and may feel faint or light-headed
- 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 have low blood pressure. You may notice this as feeling dizzy or light-headed, especially when standing up.
- if you have a narrowing of the aorta (aortic stenosis) or the heart valves (mitral valve stenosis), or an increase in the thickness of the heart muscle (known as hypertrophic cardiomyopathy).
- if you have kidney disease or narrowing of the blood vessels to the kidney
- if you need haemodialysis treatment
- if you have liver disease.
- if you have diabetes (metabolic disorder where sugar is not used properly in the body)
- if you have blood vessel disease (collagen vascular disease e.g scleroderma, SLE (lupus))
- if you are taking potassium supplements.
- if you are undergoing/or will undergo desensitisation treatment for an allergy, for example, to insect stings. The desensitisation treatment reduces the effects of the allergy (e.g. bee or wasps stings) but sometimes it can cause a more severe allergic reaction if you are taking ACE inhibitors during the desensitisation treatment.
- if you have high levels of cholesterol and you are having a treatment called ‘LDL apheresis’.
- if you are of black origin as Lestace may be less effective. You may also more readily get the side effect ‘angioedema’ (a severe allergic reaction).
- if you are going into hospital for an operation (including dental surgery). Tell your doctor or dentist that you are taking Lestace Tablets before you are given a local or general anaesthetic. Lestace Tablets, combined with some anaesthetics, may cause a short-term drop in blood pressure (hypotension) soon after taking the tablets.
- 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:
 - o Racecadotril, a medicine used to treat diarrhoea;
 - o Temsirolimus, sirolimus, everolimus and other medicines belonging to the class of mTOR inhibitors (used to avoid rejection of transplanted organs and for cancer)
 - o Vildagliptin, a medicine used to treat diabetes

You must tell your doctor if you think you are (or might become) pregnant. Lestace 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).

Note: Take special care when taking the first dose of Lestace Tablets. It may cause a greater fall in blood pressure than will occur following continued treatment. You may notice this as dizziness or light-headedness and it may help to lie down. If you are concerned, please consult your doctor.

Contact your doctor if you have high temperature, sore throat or mouth ulcers (these may be symptoms of infection caused by the lowering of the number of white blood cells) or if you notice yellowing of the skin and whites of the eyes (jaundiced) that may be a sign of a liver disease.

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 Lestace Tablets”

Other medicines and Lestace Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Some medicines may affect the actions of other medicines.

Your doctor may need to change your dose and/or take other precautions:

If you are taking an angiotensin II receptor blocker (ARB) or aliskiren (see also information under the headings “Do not take Lestace Tablets” and “Warnings and precautions”).

Talk to your doctor if you are taking any of the following medicines:

- Other medicines for your high blood pressure (antihypertensives).
- Non-steroidal anti-inflammatory medicines (NSAIDs) such as indomethacin and high doses of acetylsalicylic acid (more than 3 grams per day), which are used to treat arthritis or muscle pain.
- Water tablets (diuretic medicines).
- Beta-blocker medicines, such as atenolol and propranolol.
- Nitrate medicines (for heart problems).
- Medicines containing gold and which are administered as injection (for example sodium aurothiomalate; used to treat arthritis).
- Medicines for mental disorders such as lithium, antipsychotics or tricyclic antidepressants.
- Medicines for the treatment of diabetes, such as insulin or those taken orally, to lower blood sugar.
- Medicines that stimulate the central nervous system (sympathomimetics). These include ephedrine, pseudoephedrine and salbutamol and may be found in some decongestants, cough/cold remedies and asthma medication.
- Medicines that suppress the body’s immune response (immunosuppressants), treatment with allopurinol (for gout) or procainamide (for abnormal heartbeats).
- 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”.
- 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).

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.

Lestace Tablets with food and drink

Lestace Tablets can be taken with food and drink.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any 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 Lestace Tablets before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Lestace Tablets. Lestace Tablets are 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.

Breastfeeding

Tell your doctor if you are breast-feeding or about to start breast-feeding. Lestace Tablets are 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 Lestace Tablets

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

The dosage is individual and it is important that you take it as prescribed by your doctor. Your starting dose and long-term dose will depend on your medical condition and whether you are taking any other medicines. Once you have started taking Lestace 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 Lestace Tablets before or after food.

Keep taking Lestace for as long as your doctor tells you to, it is a long term treatment. It is important to keep taking Lestace every day.

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.

High blood pressure

The recommended starting dose is 10 mg taken once a day. The usual long-term dose is 20 mg taken once daily.

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

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 taken once a day, which can be increased to a maximum of 20 mg taken once a day.
- For children who weigh more than 50 kg, the recommended starting dose is 5 mg taken once a day, which can be increased to a maximum of 40 mg taken once a day.

Lestace is not recommended for children under 6 years or in any children with severe kidney problems.

Symptomatic heart failure

The recommended starting dose is 2.5 mg taken once a day. The usual long-term dose is 5 to 35 mg taken once daily.

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.

Kidney problems related to diabetes

The recommended dose is either 10 mg or 20 mg taken once daily.

Kidney impairment

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

If you have the impression that the effects of Lestace Tablets is too strong or too weak, talk to your doctor or pharmacist as soon as possible.

In the beginning of treatment and/or during dosage adjustment, more frequent medical check-ups may be necessary. You should not skip these visits even if you feel well. Your doctor will determine the frequency of these visits.

If you take more Lestace Tablets than you should

Contact your doctor or nearest hospital immediately if you have taken more than you should (overdose).

An overdose can cause very low blood pressure which can lead to light headedness and dizziness. Symptoms may also include shortness of breath, a rapid or slow pulse, palpitations, anxiety or coughing.

If you forget to take Lestace Tablets

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 Lestace Tablets

Do not stop taking your tablets if you are feeling well, unless your doctor tells you.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible 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 Lestace 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 (may affect up to 1 in 10 people):

Headache. Dizziness or light-headedness especially when standing up quickly. Low blood pressure. Diarrhoea, vomiting. Cough. Reduced function of the kidneys.

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

Tiredness. Weakness (loss of strength). Mood changes. Sleep disturbances. Spinning feeling (vertigo). Skin rash. Itching. Change of colour (pale blue followed by redness) and/or numbness or tingling in the fingers or toes. Running nose. Taste disturbances, feeling sick (nausea), stomach pain or indigestion. Being unable to get an erection (impotence). Awareness of heart beat, rapid heartbeat. Heart attack or stroke, 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. Seen and/or heard hallucinations.

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

Allergy/angioneurotic oedema with symptoms like swelling of the extremities, face, lips, tongue and/or throat which may cause difficulty in breathing and/or swallowing, this may be more frequent in black patients than in non-black patients. Confusion. Dry mouth. Hair loss. Psoriasis (a skin problem). Changes in the way things smell. Development of breasts in men. Renal failure. Changes to some of the cells or other parts of the blood. Itchy lumpy skin rash (hives). Increases in serum bilirubin (orange-yellow pigment in the bile). Low levels of sodium in your blood (the symptoms may be tiredness, headache, nausea, vomiting). Sudden renal failure. Uraemia (retention on the blood stream of waste products normally excreted in the urine).

Inappropriate secretion of a hormone of the brain regulating the water balance of the body (syndrome of inappropriate anti-diuretic hormone secretion/SIADH).

As mentioned above there may be changes to some of the cells or other parts of your blood. It is possible that your doctor may occasionally take blood samples to check whether Lestace Tablets has had any effect on your blood. Sometimes these changes may show themselves as tiredness or a sore throat, or they may be accompanied by a fever, joint and muscle pains, swelling of the joints or glands, or sensitivity to sunlight. If you are uncertain you should consult with your doctor.

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

Sinusitis (a feeling of pain and fullness behind your cheeks and eyes). Narrowing of the airways accompanied by shortness of breath (bronchospasm). Inflammation of the lungs (the signs include cough, feeling short of breath and high temperature (fever). Yellow skin and/or eyes (jaundice). Inflammation of the liver (this can cause loss of appetite, yellow of the skin and eyes, and dark coloured urine) or pancreas (this causes moderate to severe pain in the stomach). Liver failure. Sweating. Serious blistering skin disease (pemphigus). Skin rash (erythema multiforme), severe form of skin flushing (Steven-Johnson syndrome), severe rash involving reddening, peeling and swelling of skin equivalent to severe burns (toxic epidermal necrolysis). Lumps. Inflamed gut. Pseudolymphoma in the skin. Intestine inflammation. Passing less water (urine) than normal or passing no water. Decrease in serum glucose.

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

Fainting, depressive symptoms.

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

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.

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 Lestace Tablets

Do not store above 25°C.

Blister: Store in the original package in order to protect from moisture.

Plastic container: Keep the plastic container tightly closed in order to protect from moisture. The container contains desiccant.

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 or bottle after 'EXP'. The expiry date refers to the last day of that month.

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 Lestace Tablets contain

- The active substance is lisinopril dihydrate. Each tablet contains 2.5 mg, 5 mg, 10 mg or 20 mg lisinopril as lisinopril dihydrate.
- The other ingredients are mannitol, calcium hydrogen phosphate dihydrate, pregelatinized maize starch, croscarmellose sodium, magnesium stearate. The 10 mg and 20 mg tablets also contain: iron oxide red (E172), iron oxide black (E172) and iron oxide yellow (E172).

What Lestace Tablets look like and contents of the pack

Lestace Tablets 2.5 mg tablets are white, round and biconvex with a diameter of 6 mm.

Lestace Tablets 5 mg tablets are white, round and flat with a diameter of 8 mm, and scored on both sides.

Lestace Tablets 10 mg tablets are light pink, round and biconvex with a diameter of 7 mm, and scored on one side.

Lestace Tablets 20 mg tablets are pink, round and biconvex with a diameter of 9 mm, and scored on one side.

The tablets can be divided into equal halves.

Pack sizes:

Blister packs: 10, 14, 20, 28, 30, 50, 56, 98 and 100 tablets.

Plastic container with a desiccant and a snap-on plastic closure: 30 and 100 tablets.

Not all pack sizes may be marketed.

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