

PACKAGE LEAFLET: Information for the patient

LISIDIGAL

Tablets – 10 mg, 20 mg

(Lisinopril dihydrate)

Read all of this leaflet carefully before you start using 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 Lisidigal is and what it is used for
2. What you need to know before you take Lisidigal
3. How to take Lisidigal
4. Possible side effects
5. How to store Lisidigal
6. Further information

1. WHAT LISIDIGAL IS AND WHAT IT IS USED FOR

Lisidigal contains the active substance lisinopril, which belongs to a group of medicines called ACE inhibitors. Lisinopril lowers blood pressure and enables relaxation of the heart muscle.

Lisidigal is used in:

- treatment of high blood pressure (hypertension);
- patients whose heart function is weakened (symptomatic heart failure);
- short-term treatment (6 weeks) of patients whose blood circulation has shown stability within 24 hours of an acute myocardial infarction;

- treatment of kidney disorders in people with high blood pressure who have type 2 diabetes and previous kidney disease (nephropathy).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE LISIDIGAL

Do not take Lisidigal tablets:

- if you are allergic to lisinopril, any other ACE inhibitor, or any of the other ingredients of this medicine (listed in section 6);
- if you have ever had tissue swelling (angioedema) during previous treatments with ACE inhibitors;
- if you are born prone to having tissue swelling (hereditary angioedema) or if you have tissue swelling without any known cause (idiopathic angioedema);
- if you are more than 3 months pregnant (it is also better to avoid lisinopril 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.

Warnings and precautions

Talk to your doctor or pharmacist:

- if you suffer from any of the following disorders, or if you have any of the following conditions, please consult with your doctor before taking this medicine; he/she will consider taking the necessary precautionary measures;
- if you are at risk of having very low blood pressure; this may happen because of an imbalance in your electrolytes and body fluids, e.g. as a result of taking diuretic tablets, vomiting or diarrhoea, or as a result of having a low-salt diet;
- if you have a heart disorder which interrupts blood flow (ischemia);
- if you have any cerebrovascular disorders (that affect the flow of blood to the brain);
- if your blood flow is unstable after an acute myocardial infarction;
- if the valve in the left ventricle of your heart is narrowed, or if you have had any other problem that restrains the blood flow from the left ventricle;
- if you have impaired kidney function;

- if you have a narrowing of the renal artery (on both sides, or one side if you only have one kidney);
- if you may have allergic reactions (hypersensitivity) or tissue swelling (angioedema) during treatment with Lisidigal;
- if the liver enzymes level starts to increase, or if you develop jaundice;
- if the level of the white blood cells in your body falls (leukopenia), or if you have a major decline of certain white blood cells which makes you inclined to get infections and causing you major sickness feeling (agranulocytosis);
- if you suffer from collagen vascular disease (a type of connective tissue disorder which includes blood vessels);
- if you are being treated with drugs that suppress your body's immune response;
- if you are concomitantly taking allopurinol (a drug that treats gout), procainamide (used to treat heart rhythm disorders) or lithium (used in different types of depression);
- if your blood pressure is not adequately falling because of your ethnicity (especially Afro-Caribbean patients);
- if you have a dry and persistent cough;
- if you are at risk of high potassium levels in your blood; for example, this may happen if you have impaired kidney function, if you have diabetes mellitus, or if you are concomitantly being treated with potassium-sparing diuretic tablets, potassium supplements, salt substitutes that contain potassium or any other drug that may cause an increase in potassium levels in your serum (e.g. heparin);
- if you have diabetes (diabetes mellitus);
- if you are taking any of the following medicines used to treat high blood pressure:
 - an angiotensin II receptor blocker (ARB) (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 Lisidigal tablets”.

If you need to undergo a desensitisation treatment (to treat sensitivity) against insect venom (e.g. bees and bumblebees sting), Lisidigal must be substituted with an appropriate product from another group of drugs. Otherwise, life-threatening hypersensitivity reactions may occur (e.g. a fall in the blood pressure, breathing disorders, vomiting, skin allergic reactions). Such reactions may also happen after the insect sting (e.g. the stinger of the bee or bumblebee).

During concomitant use of Lisidigal with dialysis treatment of a certain membrane (high-flux membrane) or treatment of high levels of lipids in your blood (LDL apheresis with dextran sulfate), severe hypersensitivity reactions may occur, including life-threatening shock. Thus, if you urgently need dialysis or hemofiltration, or if you need LDL apheresis, you should first substitute Lisidigal with another drug that is appropriate for your condition – not with an ACE inhibitor – or another dialysis membrane should be used. Inform your doctor if you are taking Lisidigal or if you are undergoing dialysis, in order for them to consider it during your treatment. If you are going to have surgery or anesthesia (including dental) tell your doctor that you are taking Lisidigal. This is because you can get sudden low blood pressure during treatment with anaesthetics.

Inform your doctor immediately if you get any of the following symptoms:

- swelling of the face, extremities, lips, mucous membranes, tongue and/or larynx; difficulty breathing;
- yellowing of the skin and mucous membranes;
- fever, swollen lymphatic nodes and/or throat pain.

In case you experience any of these events, you should stop your treatment with Lisidigal and your doctor will take the appropriate measures.

Use of this medicine needs regular clinical monitoring. Thus, you need to undergo laboratory analysis and examinations assigned from your doctor.

You should inform your doctor if you think you are (or you may get) pregnant. Lisidigal is not recommended during the first months of pregnancy, and it should not be used if you are more than 3 months pregnant because it may cause serious damage to your child if it is used during this phase (see Pregnancy section).

Children and adolescents (6-16 years old) with high blood pressure

Lisidigal is not recommended in children for indications other than hypertension, in children under 6 years old, or in children with severe renal impairment ($\text{GFR} < 30 \text{ ml/min /1.73 m}^2$).

Elderly

There are no special recommendations regarding age.

However, the dose should be adjusted in older patients with reduced kidney function, depending on their blood pressure.

Other medicines and Lisidigal

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines. Some drugs can affect the way some other drugs work. Inform your doctor if you are taking any of the following drugs. Your doctor may need to change your dose and/or to take other precautions:

- diuretics (including potassium-sparing diuretics)
- other medicines to treat high blood pressure (antihypertensives)
- non-steroidal antiinflammatory drugs (NSAIDs), like indomethacin and high doses of acetylsalicylic acid (more than 3 grams daily), which are used for the treatment of arthritis or muscular pain
- medicines for mental disorders, like: lithium, anipsychotics or tricyclic antidepressants
- potassium tablets or salt substitutes containing potassium
- medicines used in the treatment of diabetes, like insulin or drugs taken orally to lower blood sugar levels
- medicines that have a stimulating effect on the central nervous system (sympathomimetics, such as ephedrine, pseudoephedrine and salbutamol); they may be found in some decongestants, drugs that treat cough and cold and drugs that treat asthma
- medicines that suppress your body's immune system (immunosuppressants), allopurinol (for gout) or procainamide (for heart problems)
- injectable gold (specific antirheumatic agents)
- angiotensin II receptor blockers (ARB) or aliskiren (see also information under the headings "Do not take Lisidigal tablets" and "Warnings and precautions");

- co-trimoxazole (trimethoprim / sulfamethoxazole) – you may have a high risk of hyperkalemia.

Pregnancy and breast-feeding

Pregnancy

You should inform your doctor if you are pregnant, you think you might be pregnant or you are planning to have a baby. Your doctor will normally advise you to stop taking Lisidigal before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Lisidigal. Lisidigal 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. Lisidigal is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breastfeed, especially if your baby is newborn, or was born prematurely.

Driving and using machines

Treatment with this medicine requires regular clinical monitoring. Different reactions may occur to some individuals, which may change the way they react to a point where it may impair their ability to drive, their ability to use machinery or carry out dangerous tasks. This happens especially at the beginning of the treatment, whenever the doctor increases your Lisidigal dose, or when your treatment is replaced with other medicines, and when alcohol is consumed during treatment with Lisidigal.

3. HOW TO TAKE LISIDIGAL

Always take this medicine exactly as your doctor or pharmacist has told you. The dose is individual and it is important that you take your medicine exactly as your doctor has told you. Your initial dose and your maintenance dose will depend on your medical condition and if you are currently taking other medicines. Check with your doctor or pharmacist if you are not sure.

Lisidigal 10 mg tablets*For high blood pressure (hypertension)*

The recommended starting dose is one 10 mg Lisidigal tablet (10 mg lisinopril) once a day. The usual maintenance dose is two 10 mg Lisidigal tablets (20 mg lisinopril) once a day.

For symptomatic heart failure

The recommended starting dose is 2.5 mg lisinopril once a day. Long term dose is $\frac{1}{2}$ to $3\frac{1}{2}$ of 10 mg Lisidigal tablets (5 mg to 35 mg lisinopril) once a day.

After an acute heart attack

The recommended starting dose is $\frac{1}{2}$ of a 10 mg Lisidigal tablet (5 mg lisinopril) on the first and second day, then one 10 mg Lisidigal tablet (10 mg lisinopril) taken once a day.

Kidney problems due to diabetes

Maintenance dose is 1 or 2 Lisidigal 10 mg tablets (10 mg or 20 mg lisinopril) once a day.

Lisidigal 20 mg tablets*For high blood pressure (hypertension)*

The recommended starting dose is $\frac{1}{2}$ of a 20 mg Lisidigal tablet (10 mg lisinopril) once a day.

The usual maintenance dose is one 20 mg Lisidigal tablet (20 mg lisinopril) once a day.

For symptomatic heart failure

The recommended starting dose is 2.5 mg lisinopril once a day. Long term dose is 5 mg to 35 mg once a day.

After an acute heart attack

The recommended starting dose is 5 mg lisinopril on the first and second day, then $\frac{1}{2}$ of a 20 mg Lisidigal tablet (10 mg lisinopril) taken once a day.

Kidney problems due to diabetes

Maintenance dose is $\frac{1}{2}$ or 1 Lisidigal 20 mg tablet (10 mg or 20 mg lisinopril) once a day.

Renal impairment

Your doctor may prescribe you a lower dose.

Use in hypertensive children and adolescents aged 6 to 16 years

For children 6 to 16 years old, the recommended starting dose is 2.5 mg lisinopril once daily in patients who weigh between 20 and 50 kg, and 5 mg lisinopril once daily in patients who weigh ≥ 50 kg. Dosage should be adjusted individually until a maximum of 20 mg lisinopril daily in patients who weigh between 20 to 50 kg, and 40 mg lisinopril in patients who weigh ≥ 50 kg. Doses higher than 40 mg lisinopril have not been studied in pediatric patients.

A lower starting dose or increase in dose interval should be taken into consideration in children with reduced renal function.

Take your tablets with water. Try to take your tablets at the same time of the day everyday. It is not important if you take your tablets before or after a meal.

If you think that the effect of Lisidigal is too strong or too weak, inform your doctor or pharmacist as soon as possible.

If you take more Lisidigal tablets than you should

Take Lisidigal according to the instructions given by your doctor or according to the instructions in this leaflet.

If you have mistakenly taken more tablets, or if a child has swallowed some of the tablets, consult a (emergency) doctor immediately. He/she will be able to decide what action to take, depending on the poisoning scale.

Depending on the range of the overdose, the following symptoms are possible:

very low blood pressure, blood circulatory shock, fast or slow heart beat, heart palpitations, renal failure, rapid breathing, dizziness, feeling anxious and cough.

If you forget to take Lisidigal

If you forget a dose, take the next dose when it is the normal time to take it. Do not take a double dose to make up for a forgotten tablet.

If you stop taking Lisidigal

Do not stop your treatment with Lisidigal tablets, unless your doctor who is following your treatment tells you to.

In hypertensive patients, blood pressure may start to increase again, whereas in patients with cardiac insufficiency, symptoms may reappear.

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.

Common (1 to 10 treated patients from 100):

- dizziness
- headache
- very low blood pressure as a result of standing up from a sitting position (orthostatic hypotension)
- cough
- diarrhoea
- vomiting
- kidney disfunction

Uncommon (1 to 10 treated patients from 1,000):

- mood changes
- unusual feeling in the skin (e.g. pinching and stinging)
- spinning feeling
- tasting disorders
- sleeping disorders
- myocardial infarction or stroke, maybe because of a marked drop in blood pressure in patients with a risk (those with blood circulation problems in heart muscle and/or brain)
- palpitations
- problems with blood circulation in your hands and feet, caused by blood vessel spasms (Raynaud's syndrome)

- inflammation of nasal mucosa (rhinitis)
- nausea
- stomach pain
- digestion issues
- skin rash
- itching
- impotence
- feeling tired
- increase in urea and creatinine serum levels
- increased levels of liver enzymes
- increased levels of potassium in blood

Rare (1 to 10 treated patients from 10,000):

- decrease in certain blood cells (hemoglobin and hematocrit)
- feeling confused
- dry mouth
- hives
- hair loss
- psoriasis
- accumulation of residues of degradation products in blood (uremia)
- acute renal failure
- enlargement of breasts in men (gynecomastia)
- increase in bilirubin levels in serum (estimation of analysis of liver function)
- increased levels of antidiuretic hormone (a hormone that helps the kidney and the body to maintain the right amount of water) (a syndrome of an unsuitable hypersecretion of the antidiuretic hormone [SIADH])
- hypersensitivity / tissue swelling (angioedema): angioneurotic edema, which affects the face, extremities, lips, tongue, glottis (an opening between the vocal cords) and/or larynx.

Very rare (less than 1 in 10,000 patients):

- decreased function of bone marrow
- anemia
- drop in certain blood cells (thrombocytopenia, leukopenia, neutropenia), including a marked drop in certain white blood cells, prone to infection and general severe symptoms (agranulocytosis)
- hemolytic anemia (caused by huge damage in red blood cells)
- swollen lymphatic nodes
- autoimmune disease
- very low blood sugar levels (hypoglycemia)
- sudden narrowing of bronchial paths (bronchospasm)
- inflammation of paranasal sinuses (sinusitis)
- lung inflammation caused by allergy (allergic alveolitis / eosinophylic pneumonia)
- pancreas inflammation
- intestine tissue swelling (intestinal angioedema)
- liver inflammation (hepatocellular or cholestatic hepatitis)
- jaundice
- liver dysfunction
- increased sweating
- allergic skin reactions (pemphigus, toxic epidermal necrolysis, Stevens-Johnson syndrome, erythema multiforme)
- a complex of symptoms is described, which may be accompanied by some of the following symptoms: fever, inflamed blood vessels (vasculitis), muscle inflammation, joint pain/inflammation and certain changes in blood test results (positive result in ANA titre, increase in erythrocyte sedimentation rate, increase in eosinophilia and leukocytosis), skin rash, light sensitivity and other possible skin reactions
- decrease in urine production (oliguria)
- lack of urine production (anuria).

What you should do if you get these symptoms

If you suspect that you are developing a serious skin reaction, you should immediately consult with your doctor and if necessary, stop your treatment with Lisidigal.

Tissue swelling (angioedema) that affects larynx, glottis (opening between the vocal cords) and/or tongue should be immediately treated by your doctor.

If you develop jaundice, or if your liver enzyme levels evidently increase, you should stop your treatment and your doctor will monitor you.

If you have fever, swollen lymphatic nodes and/or throat pain, immediately inform your doctor, so that he/she can check your number of white blood cells.

If you notice any of the above side effects, inform your doctor. He/she will determine their severity scale and further possible measures.

If you get any of these side effects, or any other side effects not listed in this leaflet, tell your doctor or pharmacist.

5. HOW TO STORE LISIDIGAL

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 blister and on the carton box.

6. FURTHER INFORMATION

What Lisidigal contains

The **active substance** is lisinopril dihydrate.

One Lisidigal 10 mg tablet contains 10 mg lisinopril (as dihydrate).

One Lisidigal 20 mg tablet contains 20 mg lisinopril (as dihydrate).

The **other ingredients** are: magnesium stearate, talc, mannitol, starch, calcium hydrogenphosphate dihydrate, croscarmellose sodium.

Contents of the pack

Carton box of 30 tablets.

Marketing Authorisation Holder (MAH) and Manufacturer:

Profarma sh.a.,

St. "Skënder Vila",

Tirana, Albania.

Tel.: +355 4 23 89 602

This leaflet was last revised in August 2023.