

Package leaflet: Information for the patient

Cordacare 10 mg tablets

(lisinopril as lisinopril dihydrate)

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 Cordacare is and what it is used for
2. What you need to know before you take Cordacare
3. How to take Cordacare
4. Possible side effects
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1. What Cordacare is and what it is used for

Cordacare contains a medicine called lisinopril and belongs to a group of medicines called ACE inhibitors.

Cordacare 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. Cordacare 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 Cordacare

Do not take Cordacare

- You are allergic to lisinopril or to other angiotensin-converting enzyme inhibitors, as well as to any of the excipients of the medicinal product.
- 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.
- 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 Cordacare 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 Cordacare.

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

Warnings and precautions

Please tell your doctor if you have had or have any of the following medical conditions:

- if you have a narrowing (stenosis) of the aorta (an artery in your heart) or a narrowing of the heart valves (mitral valves), 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 have recently had diarrhoea or vomiting;
- if you have high levels of cholesterol and you are having a treatment called LDL apheresis;
- if you are taking potassium supplements;
- you must tell your doctor if you think you are (or might become) pregnant. Cordacare 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 Cordacare may be less effective. You may also more readily get the side effect ‘angioedema’ (a severe 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.

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 Cordacare”.

Talk to your doctor if you think any of the above conditions apply to you.

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 Cordacare 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 Cordacare. This is because you can get low blood pressure (hypotension) if you are given certain local or general anaesthetics while you are taking Cordacare.

Take special care with the first dose of Cordacare. It may cause a more significant drop in blood pressure than that seen with longer treatment with the medicine. You may feel dizzy or faint, which may pass if you lie down. If this applies to you, please consult your doctor.

Other medicines and Cordacare

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines. This is because Cordacare can affect the way some medicines work and some medicines can have an effect on Cordacare. Tell your doctor or pharmacist if you are taking any of the following medicines:

- other medicines to help lower your blood pressure;
- aliskiren;

- water tablets (diuretic medicines);
- medicines to break down blood clots (usually given in a hospital);
- 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;
- 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);
- 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).

The following medicines may reduce the effect of Cordaker:

- 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 take other precautions:

- An angiotensin II receptor blocker (ARB) or aliskiren, (see also information under the headings “Do not take Lisinopril” and “Warning and precautions”).

Pregnancy, breast-feeding and fertility

Pregnancy

You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking Cordacare before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Cordacare. Cordacare 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. Cordacare 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 Cordacare

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 Cordacare your doctor may take blood tests. Your doctor may then adjust your dose so you take the right amount of medicine for you.

How to take Cordacare

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

Taking your first dose

- Take special care when you have your first dose of Cordacare 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 starting and maintenance dose will depend on your condition and whether you are taking other medicines. Ask your doctor or pharmacist if you are not sure how to take Cordaker. Your doctor will tell you how many tablets to take each day. The dosage is individual and it is very important that you take the tablets exactly as prescribed by your doctor.

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.

If you take more Cordacare than you should

If you take more Cordacare than prescribed by your doctor, talk to a doctor or go to a hospital immediately.

If you forget to take Cordacare

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 Cordacare

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 Cordacare and see your doctor immediately.

Signs of such reactions are as follows:

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;
- Being sick (vomiting);
- A dry cough that does not go away;
- 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;
- 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;
- Hallucinations.

Rare (affects 1 user 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 Cordacare 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.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system of Bulgarian Drug Agency. By reporting side effects you can help provide more information on the safety of this medicine.

Contacts:

Bulgarian Drug Agency
8 Damyan Gruev Str.,
1303 Sofia.
Tel.: +359 2 890 3417
Website: www.bda.bg

5. How to store Cordacare

This medicinal product does not require any special storage conditions.

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.

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 Cordacare contains**

- The active substance is lisinopril (as lisinopril dihydrate)
- The other ingredients are: mannitol and others.

What Cordacare looks like and contents of the pack

Cordacare 10 mg available in PVC / AL blisters of 30 pieces (3 blisters of 10 tablets) in a cardboard box with a patient leaflet.

Marketing Authorisation Holder and Manufacturer:

Tchaikapharma High Quality Medicines Inc.
1 G. M. Dimitrov Blvd, Sofia 1172, Bulgaria
Tel.: + 359 2 962 54 54
FAX: + 359 2 9603 703
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For any information about this medicine, please contact the Marketing Authorization Holder:

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