

Package leaflet: Information for the patient

Enalapril-Tchaikapharma 5 mg tablets (*Enalapril maleate*)

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 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

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1. What Enalapril-Tchaikapharma is and what it is used for

Enalapril-Tchaikapharma contains active substance enalapril maleate. It belongs to the class of medicines called Angiotensin converting enzyme inhibitors (ACE inhibitors), which widening blood vessels, making it easier for the heart to pump blood to all parts of the body. This lowers high blood pressure. In patients with heart failure, Enalapril-Tchaikapharma helps the heart to function better.

Enalapril-Tchakapharma is used:

- To treat high blood pressure (hypertension);
- To treat heart failure
- Prevention of symptomatic heart failure in asymptomatic patients with left ventricular dysfunction (ejection fraction $\leq 35\%$)

2. What you need to know before you take Enalapril-Tchaikapharma

Do not take Enalapril-Tchaikapharma:

- If you are allergic (hypersensitive) to enalapril maleate, any of the other ingredients in these tablets (see Section 6).
- If you have had allergic reactions such as swelling of the face, lips, tongue and / or throat, with difficulty breathing and swallowing, with previous treatment with medicines such as Enalapril-Tchaikapharma (ACE inhibitors). You should not take Enalapril-Tchaikapharma if you have had such reactions for no known reason or if you have been diagnosed with congenital or idiopathic angioedema.
- If you are more than 3 months pregnant. (It is also better to avoid Enalapril maleate 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.

Warnings and precautions

Talk to your doctor or pharmacist before taking Enalapril-Tchaikapharma.

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, etc.), 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 Enalapril-Tchaikapharma”.

Before you start taking Enalapril-Tchaikapharma, tell your doctor about all your medical problems, as well as any allergies.

Tell the doctor if you have heart disease, if you are on dialysis or are being treated with diuretics (drugs that increase the secretion of body water), if you have been very sick (excessive vomiting) or had bad diarrhoea recently. You must also state whether you are on a salt-restricted diet, are taking potassium supplements, potassium-sparing agents, potassium-containing salt substitutes, if you have diabetes or a kidney problem (including kidney transplantation). These may lead to higher levels of potassium in your blood which can be serious. Your doctor may need to adjust your dose of Innovace or monitor your blood level of potassium.

Tell your doctor if you notice symptoms such as nausea or dizziness, especially when standing up, which indicate low blood pressure (orthostatic hypotension).

If you have diabetes and you are taking oral antidiabetic medicines or insulin, you should monitor your blood glucose levels regularly, especially during the first month of treatment with Enalapril-Tchaikapharma..

If you have blood disorders, such as a reduced number or absence of white blood cells (neutropenia / agranulocytosis), a reduced number of platelets (thrombocytopenia) or a reduced number of red blood cells (anemia).

If you have liver problems, you are going to be desensitized (reduces the effects of allergies, eg from bee and wasp bites), you are undergoing hemodialysis or treatment to remove cholesterol from your body using a machine (LDL apheresis).

Tell your doctor if you have ever had allergic reactions with swelling of the face, lips, tongue and / or throat with difficulty swallowing and breathing.

Before surgery or anesthesia (even during dental procedures), tell your surgeon or dentist that you are taking Enalapril-Tchaikapharma. This is necessary because a sudden drop in blood pressure may occur during anesthesia.

Cough may occur with ACE inhibitors, including Enalapril-Tchaikapharma. It is dry, prolonged and subsides after stopping treatment.

Elderly patients

Data from clinical trials on efficacy and tolerability in the elderly and younger patients show no differences.

Black patients

Like other ACE inhibitors, enalapril is less effective in lowering blood pressure in black patients than in non-black patients..

Pregnancy

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

Breast-feeding

Tell the doctor if you are breastfeeding or you are breastfeeding (see. Section Lactation).

Other medicines and Enalapril-Tchaikapharma

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Also some other medicines can affect the way Enalapril-Tchaikapharma works.

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

- diuretics (medicines that increase fluid excretion, including potassium-sparing diuretics).
- medicines containing potassium (including dietary salt substitutes) o.
- other medicines for high blood pressure (antihypertensive medicines).
- Medicines for mental problems such as lithium, antipsychotic or tricyclic antidepressants.
- non-steroidal anti-inflammatory drugs (NSAIDs), which are used to treat arthritis or muscle pain.
- certain pain or arthritis medicines including gold therapy.
- medicines for insomnia and anxiety (sleeping pills and sedatives).
- medicines for diabetes (including oral antidiabetic medicines and insulin).
- certain cough and cold medicines and weight reducing medicines which contain something called a 'sympathomimetic agent'.
- alcohol.

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

an angiotensin II receptor blocker (ARB) or aliskiren (see also information under the headings "Do not take Innovace" and "Warnings and precautions")

Enalapril-Tchaikapharma with food, drink and alcohol

Enalapril-Tchaikapharma can be taken with or without food. Most people take Innovace with a drink of water.

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 Innovace before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Innovace. This medicine 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. Breast-feeding newborn babies (first few weeks after birth), and especially premature babies, is not recommended whilst taking this medicine. In the case of an older baby your doctor should advise you on the benefits and risks of taking this medicine whilst breast-feeding, compared to other treatments.

Driving and using machines

You may feel dizzy or sleepy while taking this medicine. If this happens, do not drive or use any tools or machines.

Enalapril-Tchaikapharma contains lactose

If you know you have intolerance to some sugars, contact your doctor before use.

3. How to take Enalapril-Tchaikapharma

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

The dosage and duration of treatment are determined by the treating physician, and are individual depending on the effect, tolerability and intake of other drugs. It is taken before, during or after a meal, by mouth with a sufficient amount of liquid.

Enalapril-Tchaikapharma treatment is usually long-term, the duration of which is determined by your doctor. Do not take more than the prescribed tablets.

High blood pressure

- The usual starting dose ranges from 5 to 20 mg taken once a day.
- Some patients may need a lower starting dose.
- The usual long term dose is 20 mg taken once a day.
- The maximal long term dose is 40 mg taken once a day.

Heart failure

- The usual starting dose is 2.5 mg taken once a day.
- Your doctor will raise this amount step by step until the dose that is right for you has been achieved.
- The usual long term dose is 20 mg each day, taken in one or two doses.
- The maximal long term dose is 40 mg each day, divided in two doses.

Take special care with your first dose or if your dose has been increased. If you experience symptoms such as dizziness or vertigo, tell your doctor immediately.

Patients with kidney problems

Your dose of medicine will be changed depending on how well your kidneys are working.

- moderate kidney problems – 5 mg to 10 mg each day.
- severe kidney problems - 2.5 mg each day.
- if you are having dialysis - 2.5 mg each day. On days you are not having dialysis, your dose may be changed depending on how low your blood pressure is.

Elderly patients

Your dose will be decided by your doctor and will be based on how well your kidneys are working.

Use in children

Experience in the use of Enalapril-Tchaikapharma in children with high blood pressure is limited. If the child can swallow tablets, the dose will be worked out using the child's weight and blood pressure. The usual starting doses are:

- between 20 kg and 50 kg - 2.5 mg each day
- more than 50 kg – 5 mg each day.

The dose can be changed according to the needs of the child:

- a maximum of 20 mg daily can be used in children who are between 20 kg and 50 kg.
- a maximum of 40 mg daily can be used in children who are more than 50 kg.

This medicine is not recommended in newborn babies (first few weeks after birth) and in children with kidney problems.

If you take more Enalapril-Tchaikapharma than you should

If you take more Enalapril-Tchaikapharma than you should, contact your doctor.

The most common symptoms of overdose are dizziness, vertigo (due to a sudden or severe drop in blood pressure), confusion and decreased urine output.

In case of overdose it is necessary to stop taking the product, to do gastric lavage and to appoint activated charcoal and symptomatic agents. The patient should be monitored by a physician until all symptoms have resolved.

If you forget to take Enalapril-Tchaikapharma

If you forget to take a tablet, skip the missed dose. Take the next dose as usual. Do not take a double dose to make up for a forgotten dose.

If you stop taking Enalapril-Tchaikapharma

Do not stop taking your medicine 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 are not sure what the side effects listed below are, ask your doctor to explain them to you.

Stop taking Enalapril-Tchaikapharma and talk to a doctor straight away, if you notice any of the following:

- allergic reactions – swelling of your face, lips, tongue or throat which may cause difficulty in breathing or
- swallowing.
- swelling of your hands, feet or ankles.
- if you develop a raised red skin rash (hives).

Stop taking Enalapril-Tchaikapharma and talk to a doctor straight away, if you notice any of the following:

- Severe dizziness and nausea, especially at the beginning of treatment or when increasing the dose, as well as when standing up; severe reddening of the skin, blistering, severe peeling of the skin.

Other possible side effects include:

Very common (may affect more than 1 in 10 people)

- Feeling dizzy, weak or sick;
- Blurred vision;
- Cough.

Common (may affect up to 1 in 10 people)

- headache, depression;
- low blood pressure, syncope, changes in heart rhythm, fast heartbeat, angina or chest pain;
- shortness of breath;
- diarrhoea, abdominal pain, change in sense of taste;
- rash, hypersensitivity/angioneurotic edema (severe life-threatening allergic reaction): angioneurotic edema (swelling) of the face, limbs, lips, tongue, throat, difficulty swallowing and shortness of breath;

- tiredness (fatigue);
- high levels of potassium in the blood, increased levels of creatinine in your blood.

Uncommon (may affect up to 1 in 100 people)

- anaemia, low level of blood sugar;
- confusion, sleeplessness or sleepiness, nervousness, feeling your skin prickling or being numb, vertigo;
- low blood pressure (which may cause dizziness when standing up), heart skipping, heart attack or stroke in high-risk patients);
- runny nose, sore throat or hoarseness, asthma-associated tightness in chest;
- slow movement of food through your intestine (ileus), inflammation of your pancreas, being sick (vomiting), indigestion, constipation, anorexia, irritated stomach (gastric irritations), dry mouth, ulcer;
- increased sweating, itching or nettle rash, hair loss;
- impaired kidney function, kidney failure, proteins in your urine (measured in a test);
- impotence;
- muscle cramps, redness of the skin, ringing in your ears, malaise, fever;
- low level of blood sugar or sodium, high level of blood urea (all measured in a blood test).

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

- changes in the number of different blood cells (decrease in white and red blood cells and platelets), enlarged lymph nodes, bone marrow depression, autoimmune diseases;
- strange dreams or sleep problems;
- Raynaud's phenomenon' where your hands and feet may become very cold and pale due to low blood flow;
- inflammation of the lungs, runny nose, eosinophilic pneumonia (expressed as cough, fever and difficulty breathing);
- inflammation of the cheeks, gums, tongue, lips, throat;
- impaired liver function or hepatitis, which may cause yellowing of the skin (jaundice));
- Stevens-Johnson syndrome' and 'toxic epidermal necrolysis' (serious skin conditions where you have reddening and scaling of your skin, blistering or raw sores), exfoliative dermatitis/erythroderma (severe skin rash with flaking or peeling of the skin), pemphigus (small fluid-filled bumps on the skin);
- reduced amount of urine;
- enlargement of breasts in males (gynaecomastia);
- high levels of liver enzymes or bilirubin (blood counts for liver damage).

Very Rare (may affect up to 1 in 10 000 people)

- swelling in your intestine (intestinal angioedema) – symptoms may include abdominal pain, malaise and vomiting.

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

- overproduction of antidiuretic hormone.

Other

A symptom complex has been reported which may include some or all of the following:

- fever, inflammation of the blood vessels, muscle pain, joint pain.
- blood disorders (detected by blood tests).
- rash, photosensitivity or other skin manifestations may occur.

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 the national reporting system of Bulgarian Drug Agency

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

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Enalapril-Tchaikapharma

Do not store above 25°C. Store in the original package in order to protect from moisture. 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 the carton 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 Enalapril-Tchaikapharma contains

- The active substance is enalapril maleate.
- The other ingredients are lactose monohydrate, sodium hydrogen carbonate, maize starch, croscarmellose sodium, pregelatinized starch, magnesium stearate, iron oxide red E172.

What Enalapril-Tchaikapharma looks like and contents of the pack

Enalapril-Tchaikapharma is available in cartons containing 3 blister strips of 10 tablets, a total of 30 tablets per box, or 2 blister strips of 10 tablets, a total of 20 tablets per box.

Marketing Authorisation Holder and manufacturer

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For any information about this medicine, please contact the Marketing Authorization Holder:

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