

 PACKAGE LEAFLET:
Information for the user

ENALAPRIL

Tablets – 20 mg

(Enalapril maleate)

Read this leaflet carefully before you start taking this medicine.

- 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 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.

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1. WHAT ENALAPRIL IS AND WHAT IT IS USED FOR
Enalapril, after hydrolysis to enalaprilat, blocks angiotensin converting enzyme (ACE) in humans. ACE is a peptidyl dipeptidase that inhibits the conversion of angiotensin I to angiotensin II, which is a powerful vasoconstrictor substance that stimulates the secretion of aldosterone by the adrenal cortex. The benefits of the effects of enalapril in hypertension and heart failure, are thought to be primarily due to the inhibition of the renin-angiotensin-aldosterone system.

Enalapril is used in:

- essential and renovascular hypertension;
- congestive heart failure;
- prevention of symptomatic heart failure in patients with asymptomatic left ventricular dysfunction.

Your doctor may have given Enalapril for another purpose. Ask your doctor if you want to know why you were given Enalapril.

2. BEFORE YOU TAKE ENALAPRIL

Do not take Enalapril if you are:

- allergic to enalapril maleate; allergic to any of the inactive ingredients listed at the end of this leaflet;
- a patient with a history of angioedema caused by treatment with an ACE - inhibitor;
- a patient with a history of hereditary and idiopathic angioedema;
- during the second and third trimester of pregnancy;
- a patient with diabetes mellitus or renal impairment who takes aliskiren - containing products.

If you notice that you have any of the conditions mentioned above, do not take the tablets, talk to your doctor first and follow his advices.

Take special care with Enalapril

Inform your doctor if:

- you are allergic to other drugs, especially if they are in the same class with Enalapril;
- you are or plan to become pregnant while you are taking Enalapril, mainly during the second and third trimester of pregnancy;
- you are taking diuretics, suffer from heart failure, are dehydrated, are keeping a restricted salt diet or doing hemodialysis because enalapril maleate after the first dose causes hypotension and should be used with caution;
- you suffer from general arteriosclerosis or peripheral vascular disease;
- you have aortic or mitral valve stenosis or hypertrophic cardiomyopathy;
- you have renal function impairment, including renal artery stenosis; the dose should be reduced, renal function should also be monitored before and during treatment;
- you have liver problems;

- you have disorders that affect myocardial blood supply (ischemia) or cerebrovascular disorders;
- you have a low number of white blood cells, red cells or platelets;
- you suffer from collagen vascular disease (regular blood counts are necessary), are on therapy that suppresses your immune system, are taking allopurinol or procainamide;
- you are taking any of the following medicines used to treat high blood pressure: angiotensin II receptor antagonists or aliskiren;
- you have Afro - Caribbean ethnic backgrounds (the response to ACE inhibitors may be lower);
- you suffer from primary aldosteronism (may respond less well to the treatment with ACE inhibitors);
- you have had an allergic reaction before (black patients are at increased risk of these type of reactions);
- you are taking potassium supplements or potassium containing salt substitutes;
- you have diabetes (it is necessary to monitor your blood glucose levels, especially during the first month);
- you are about to have procedures like: dialysis with high-flux polyacrylonitrile membranes and LDL apheresis with dextran sulfate or desensitisation with wasp / bee venom; ACE inhibitors should be avoided in these cases to prevent anaphylactoid reactions;
- you will undergo a surgical or anesthetic intervention.

Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription, such as:

- aliskiren and angiotensin-II receptor antagonists: increased risk of hyperkalaemia, hypotension, and impaired renal function;
- alprostadil, anesthetics, antidepressants, antipsychotics, anxiolytics and hypnotics, beta-blockers, calcium-channel blockers, diuretics, dopaminergics (levodopa), nitrates, thymoxamine: the hypotensive effect is increased;
- antacids: inhibit the absorption of enalapril;
- analgesics, corticosteroids, epoetin: the hypotensive effect is antagonised;
- antidiabetics: increase the possibility of a hypoglycemic effect;
- cyclosporin, potassium-sparing diuretics, aldosterone antagonists, epoetin, anticoagulants (heparin), potassium salts: the risk of hyperkalaemia is increased;
- lithium: enalapril reduces the elimination of lithium (increased concentration of lithium in plasma);
- drugs known as "sympathomimetics" that are used against cough, cold, weight loss etc.;
- bee or wasp venom extracts: severe anaphylactoid reactions may appear when taken concomitantly with ACE inhibitors;
- cytotoxics: increased risk of angioedema when ACE inhibitors are taken with everolimus;
- sodium aurothiomalate: flushing and hypotension are reported when taken concomitantly with ACE inhibitors.

These medicines may be affected by Enalapril or they may affect the way it acts. During their concomitant use, the decrease or increase of enalapril dose is required. Your doctor or pharmacist will advise you.

Taking Enalapril with food and drinks

Alcohol may interact with Enalapril by increasing the hypotensive effect, therefore it should not be consumed during the time of treatment.

Pregnancy

Inform your doctor or pharmacist if you are pregnant or planning to become pregnant. Enalapril should be avoided during pregnancy, especially during the second and third trimester (Category D).

Breastfeeding

Inform your doctor or pharmacist if you are breastfeeding. Your doctor or pharmacist will discuss the risks and benefits of taking enalapril if you are breastfeeding or planning to breastfeed.

Enalapril should be avoided in the first weeks after birth because it can cause hypotension in infants.

Driving and using machines

Be careful when driving or using machines because this medicine may cause dizziness and fatigue.

Important information about some of the excipients of Enalapril

This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. HOW TO TAKE ENALAPRIL

Always take Enalapril exactly as your doctor has told you. If you are not sure, contact your doctor or pharmacist. If you feel that Enalapril effects are too strong or too weak, talk to your doctor or pharmacist. The tablets should be swallowed with at least half glass of water.

The dosage of Enalapril is as follows:

In the treatment of hypertension, an initial dose of 5 mg of enalapril maleate daily may be given by mouth. 2.5 mg daily should be given to patients with renal impairment or to those who are receiving a diuretic; if possible, the diuretic should be withdrawn 2 or 3 days before enalapril is started and resumed later if necessary. The maintenance dose is 10 mg to 20 mg given once daily, although doses of up to 40 mg daily may be required in severe hypertension. It should be given in two divided doses if control is inadequate with a single dose. In patients with heart failure or asymptomatic left ventricular dysfunction enalapril maleate is given by mouth in an initial dose of 2.5 mg daily. The maintenance dose is 20 mg daily as a single dose or in 2 divided doses, although doses up to 40 mg daily may be required in severe hypertension, in 2 divided doses.

Ask your doctor for advice if you are not sure for the way of use.

If you take more Enalapril than you should

If you take more Enalapril than you should, or if the children take it accidentally, please contact your doctor, the hospital or any medical care site to seek advice on the risk and the appropriate measures to be taken.

If you forget to take Enalapril

If you forget to take one dose, take the next dose in its usual time. Do not take a double dose to make up a forgotten dose. If you have further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Enalapril can cause side effects, although not everybody gets them. Sometimes they are serious, most of the time not. Do not get alarmed by this list of possible side effects. You may not get any of them.

Stop the treatment and inform your doctor straight away, if any of the following side effects appears to you:

- swelling of your face, lips, tongue or throat, which cause difficulty in breathing or swallowing;
- swelling of your hands, feet or ankles;
- redness, urticaria.

When you start taking this medicine, you may have dizziness or feel faint as a result of your blood pressure lowering. This situation improves as you continue to take the medicine.

Other side effects include:

Very Common (may affect more than 1 in 10 people)
Feeling dizzy, weak or sick, blurred vision, dry cough.

Common (may affect up to 1 in 10 people)

Light-headedness due to low blood pressure, changes in heart rhythm, fast heartbeat, angina or chest pain, headache, depression, fainting (syncope), change in the sense of taste, shortness of breath, diarrhoea, abdominal pain, tiredness (fatigue), rash, allergic reactions with swelling of the face, lips, tongue or throat with difficulty in swallowing or breathing, high levels of potassium in the blood, increased levels of creatinine in your blood.

Uncommon (may affect up to 1 in 100 people)

Flushing, sudden fall in blood pressure, fast or uneven heart beats (palpitations), heart attack (possibly due to very low blood pressure in certain high-risk patients, including those with blood flow problems of the heart or brain), stroke (possibly due to very low blood pressure in high-risk patients), anaemia (including aplastic and haemolytic), confusion, sleeplessness or sleepiness, nervousness, feeling your skin prickling or being numb, vertigo (spinning sensation), ringing in the ears (tinnitus), runny nose, sore throat or hoarseness, asthma-associated tightness in chest, slow movement of food through intestine (ileus), inflammation of pancreas, being sick

(vomiting), indigestion, constipation, anorexia, irritated stomach (gastric irritations), dry mouth, ulcer, muscle cramps, impaired kidney function, kidney failure, increased sweating, itching or urticaria, hair loss, generally feeling unwell (malaise), high temperature (fever), impotence, high level of proteins in urine, low level of blood sugar or sodium, high level of blood urea.

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

Raynaud's phenomenon where hands and feet may become cold and white due to low blood flow, changes in blood values such as a lower number of white and red blood cells, low haemoglobin, low number of blood platelets, bone marrow depression, swollen glands in neck, armpit or groin, autoimmune diseases, strange dreams or sleep problems, accumulation of fluid or other substances in lungs, inflammation of nose, inflammation of the lungs causing difficulty breathing (pneumonia), inflammation of the cheeks, gums, tongue, lips, throat, reduced amount of urine, erythema multiforme, Stevens-Johnson syndrome and toxic epidermal necrolysis (serious skin conditions where it is noticed reddening and scaling of the skin, blistering or raw sores), pemphigus (small fluid-filled bumps on the skin), enlargement of breasts in males (gynaecomastia), liver or gallbladder problems such as lower liver function, inflammation of your liver, jaundice (yellowing of the skin or eyes), high levels of liver enzymes or bilirubin. Due to reports of cholestatic jaundice, hepatitis, fulminant hepatic necrosis and liver failure, Enalapril should be discontinued if jaundice or a significant increase of hepatic enzymes occurs.

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

Swelling in your intestine (intestinal angioedema).

Other effects

Overproduction of antidiuretic hormone, which causes fluid retention, resulting in weakness, tiredness or confusion, a symptom complex which may include some or all of the following: fever, inflammation of the blood vessels (serositis / vasculitis), muscle pain (myalgia / myositis), joint pain (arthralgia / arthritis). Rash, photosensitivity or other skin manifestations may occur.

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

5. HOW TO STORE ENALAPRIL

Keep out of the sight and reach of children!
Do not take Enalapril after the expiry date which is stated on the package.
Do not store above 25°C!
Keep in the original package to protect from light and humidity!

6. OTHER INFORMATION

What Enalapril – Tablets 20 mg contain:

The active substance is enalapril maleate.

Each tablet contains 20 mg of enalapril maleate.

The other ingredients: maize starch, lactose monohydrate, microcrystalline cellulose, maleic acid, magnesium stearate, Sicovit yellow E 172 (colouring agent).

Content of the pack

Carton box with 30 tablets.

Explanatory of the illustration icons on the packaging:

 Ask your doctor or pharmacist.

 Content.  Warning.

 Tablet shape.

Marketing Authorisation Holder (MAH) and Manufacturer:

 **PROFARMA Sh.a.**
Rruga "Myslym Keta"
Tel.: 00355 4 23 89 602
Tirana - ALBANIA

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