

Package leaflet: Information for the user

Enalapril Maleate 5 mg, 10 mg, and 20 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 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 or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

- 1. What Enalapril Maleate is and what it is used for**
- 2. What you need to know before you take Enalapril Maleate**
- 3. How to take Enalapril Maleate**
- 4. Possible side effects**
- 5. How to store Enalapril Maleate**
- 6. Contents of the pack and other information**

1. What Enalapril Maleate is and what it is used for

- Enalapril Maleate belongs to a group of drugs called Angiotensin Converting Enzyme (ACE) Inhibitors which are vasodilators (drugs which widen the blood vessels). This lowers your blood pressure.
- This medicine works by widening the blood vessels, making it easier for the heart to pump blood around the body. This helps to lower blood pressure.
- Enalapril Maleate is used:
 - in the treatment of high blood pressure
 - in the treatment of heart failure. This is when your heart is not coping with its workload properly. This can make you feel tired after light exercise, breathless, or cause swelling of your ankles or legs. This medicine should improve your symptoms, prevent your heart failure from getting worse and reduce the likelihood that you will need to go into hospital for the treatment of heart failure
 - To prevent the signs of heart failure in patients with asymptomatic left ventricular dysfunction. The signs include shortness of breath, tiredness after light physical activity such as walking, or swelling of the ankles and feet.

2. What you need to know before you take Enalapril Maleate

DO NOT take Enalapril Maleate:

- if you are allergic to Enalapril Maleate, any other ACE-inhibitor or any of the other ingredients of this medicine (listed in section 6.).
- if you have ever experienced an allergic reaction to an ACE-inhibitor drug e.g. captopril, ramipril
- if you have ever experienced an allergic reaction involving swelling of hands, lips, tongue or throat
- if you are more than 3 months pregnant (it is also better to avoid Enalapril Maleate in early pregnancy – see section 2: Pregnancy and breast-feeding)
- if you were born with a tendency for tissue swelling (hereditary angioedema) or if you have tissue swelling with no known cause (idiopathic angioedema)

- 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.

Do not take Enalapril maleate if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Enalapril maleate.

Warnings and precautions Talk to your doctor or pharmacist before taking Enalapril maleate:

- If you may be dehydrated, for example, you have suffered from excessive vomiting or diarrhoea recently
- If you suffer from narrowing of the blood vessels leading to your kidneys
- If you have a condition called ‘aortic stenosis’ or ‘outflow obstruction’ (a narrowing of the main artery leading from your heart)
- If you have any other serious heart problems (apart from heart failure) or suffer from cerebrovascular insufficiency (insufficient blood supply to the brain)
- If you suffer from kidney problems or you are on dialysis
- If you have had a kidney transplant
- If you suffer from liver problems
- If you are diabetic. You should monitor your blood for low blood glucose levels, especially during the first month of treatment. The level of potassium in your blood can also be higher.
- If you have previously had an allergic reaction with swelling of the face, lips, tongue or throat with difficulty in swallowing or breathing. You should be aware that black patients are at increased risk of these types of reactions to ACE inhibitors.
- If you have low blood pressure (you may notice this as faintness or dizziness, especially when standing)
- If you are on a low salt diet, are taking potassium supplements, potassium- sparing agents or potassium containing salt substitutes.
- If you suffer from a collagen vascular disease such as lupus erythematosus, rheumatoid arthritis or scleroderma, are on therapy that suppresses your immune system, are taking the drugs allopurinol or procainamide, or any combinations of these.
- If you have a blood problem that includes one of the following: low white blood cells count, low platelet count or decreased number of red blood cells (anaemia)
- If you are breast feeding or about to start breast-feeding (see section 2: Pregnancy and breast-feeding)
- if you are taking any of the following medicines, the risk of angioedema (rapid swelling under the skin in area such as the throat) may be increased:
 - Medicines used to prevent organ transplant rejection and for cancer (e.g., temsirolimus, sirolimus, everolimus)
 - racecadotril, a medicine used to treat diarrhoea
 - vildagliptin, a medicine used to treat diabetes
- 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 Enalapril Maleate’.

You must tell your doctor if you think you are **(or might become)** pregnant. Enalapril Maleate 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 section 2: Pregnancy and breast-feeding).

Other precautions you should remember whilst taking this medicine:

- If you are about to have a treatment called ‘LDL apheresis’, which is the removal of cholesterol from your blood by a machine, you should tell the doctor who is treating you that you are taking Enalapril Maleate. The doctor may wish to stop your medicine to prevent a possible allergic reaction.
- If you are to undergo any desensitisation treatment to reduce the effects of an allergy to bee or wasp stings, you should tell the doctor before treatment that you are taking Enalapril Maleate. The doctor may wish to stop your medicine to prevent a possible allergic reaction.
- If you are going to have an anaesthetic (even at the dentist) or undergo any surgery you should tell the doctor or dentist treating you that you are taking Enalapril Maleate.

Other medicines and Enalapril Maleate

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because Enalapril maleate can affect the way some medicines work and some other medicines can affect the way Enalapril maleate works.

In particular, talk to your doctor if you are taking any of the following:

- diuretics (also known as ‘water tablets’) e.g. amiloride, spironolactone, eplerenone or triamterene
- 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).
- other medicines to lower blood pressure e.g. nitroglycerin
- non-steroidal anti-inflammatory drugs, including COX-2 inhibitors (usually taken to relieve pain, inflammation and/or stiffness) e.g. ibuprofen or diclofenac
- anti-diabetic medicines, tablets as well as insulins
- hypnotics (medicines to help you sleep) e.g. temazepam
- narcotics (medicines used to relieve moderate to severe pain) e.g. morphine or pethidine
- tricyclic antidepressants e.g. amitriptyline
- antipsychotics (medicines to treat schizophrenia, manic depression and paranoia) e.g. chlorpromazine, haloperidol, clozapine
- lithium (used to treat depression)
- allopurinol (used to treat gout)
- racecadotril (a medicine used to treat diarrhoea)
- procainamide (used to treat some heart conditions)
- sympathomimetics e.g. dopamine, terbutaline, salmeterol, salbutamol, ephedrine, adrenaline or phenylpropanolamine (phenylpropanolamine and ephedrine may be present in medicines for colds and nasal stuffiness)
- therapy with gold
- acetylsalicylic acid (aspirin)
- thrombolytics (medicines used to dissolve blood clots)
- alcohol
- 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”.

- Your doctor may need to change your dose and/or to take other precautions: If you are taking an angiotensin II receptor blocker (ARB) or aliskiren (see also information under the headings ‘Do not take Enalapril Maleate’ and ‘Warnings and precautions’)

Enalapril Maleate with food, drink and alcohol

- Enalapril maleate can be taken with or without food.
- You should keep your alcohol intake to a minimum while you are taking this medicine, as alcohol increases the blood pressure lowering effects of Enalapril Maleate, and this medicine may increase the effects of alcohol.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

- DO NOT take Enalapril Maleate if you are more than 3 months pregnant.
- You must tell your doctor if you think you are (**or might become**) pregnant. Your doctor will normally advise you to stop taking Enalapril Maleate before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Enalapril Maleate. Enalapril Maleate 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 Enalapril Maleate.
- In the case of an older baby your doctor should advise you on the benefits and risks of taking Enalapril Maleate whilst breast-feeding, compared with other treatments.

Driving and using machines

- Enalapril Maleate may cause blurred vision, dizziness or weariness. If you are affected, DO NOT drive or operate machinery.

Enalapril Maleate contains lactose and sodium

- Enalapril Maleate contains lactose, which is a type of sugar. If you have been told by your doctor that you have intolerance to some sugars, talk to your doctor before taking this medicine.
- This medicinal product contains less than 1 mmol sodium (23 mg) per tablet, i.e. essentially ‘sodium-free’.

3. How to take Enalapril Maleate

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 tablets should be swallowed preferably with a drink of water. The tablets should usually be taken once a day, in the morning, but your doctor may ask you to take them twice a day e.g. in the morning and in the evening. The recommended dose for:

- **Adults:**
High Blood Pressure

Treatment will usually start with 5 –20 mg per day. This may be gradually increased to a maintenance dose of 20 mg per day. The maximum maintenance dose is 40 mg per day.

Heart Problems

Treatment will usually start with 2.5 mg per day. This may be gradually increased to a maximum dose of 40 mg per day given in divided doses. The usual long term dose is 20 mg each day, taken in one or two doses.

Dialysis patients

On dialysis days, you should take your usual dose **after dialysis**.

- **Older patients or patients with kidney problems:**
If you are elderly or have kidney problems the dose may be lower.
- **Use in children and adolescents:**
Experience with the use of this medicine in children with high blood pressure is limited.

For children who can swallow the tablets, Enalapril Maleate is given once a day.

The doctor will decide the dose depending on the child's weight and blood pressure response. As a guide, the recommended initial dose is:

- **children weighing from 20 kg to 50 kg** = 2.5 mg
- **children weighing over 50 kg** = 5 mg

The maintenance dosage should be adjusted according to the needs of the child to a maximum of 20 mg daily in children weighing 20 kg to 50kg and 40 mg in children weighing over 50 kg. Enalapril Maleate is not recommended in babies or children with kidney problems.

If you take more Enalapril Maleate than you should

If you (or someone else) swallow a lot of the tablets all together or if you think a child has swallowed any of the tablets, contact your nearest hospital casualty department or your doctor immediately. An overdose is likely to cause low blood pressure and you may feel light headed and dizzy. Please take this leaflet, any remaining tablets and the container with you to the hospital or doctor so that they know which tablets were consumed.

If you forget to take Enalapril Maleate

If you forget to take a tablet, take one as soon as you remember, unless it is nearly time to take the next one. Do not take a double dose to make up for a forgotten dose.

If you stop taking Enalapril Maleate

DO NOT stop taking your medicine without talking to your doctor first even if you feel better. If you see another doctor or go into a hospital, let the doctor or the staff know what medicines you are taking. 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.

You may feel dizzy or, visual problems, light-headed for a short time after you take your first dose, or when you first take an increased dose. It may help to lie down until you feel better. If you are worried, or if these effects continue, talk to your doctor or pharmacist.

Stop taking the tablets and tell your doctor immediately or go to the casualty department at your nearest hospital if you experience any of the following side-effects:

- an allergic reaction causing itchy, raised rash, swelling of the lips, face, tongue or neck leading to severe difficulty in breathing or severe skin rash or hives
- blisters which may burst easily becoming raw and painful or may bleed, red itchy spots, peeling skin leaving red raw patches over the body, blisters/bleeding of the lips, eyes, nose, mouth and genitals.
- a swollen painful abdomen, constipation, being sick, indigestion, loss of appetite, dry mouth; this could be a sign of an obstruction or blockage of the bowel
- severe pain in the abdomen and back; this could be a sign of pancreatitis
- blood disorders including anaemia (low blood count causing unusual tiredness or weakness) or bone marrow problems. Symptoms may include fever, chills, sore throat, ulcers in your mouth or throat or unexplained bruising or bleeding
- lung problems including inflammation of the lung (pneumonia). You may feel unwell or less hungry, have a high temperature (fever) difficulty breathing, shortness of breath, cough
- high temperature, tiredness, loss of appetite, stomach pain, feeling sick, jaundice (yellowing of the skin or whites of the eyes), liver failure. These may be symptoms of hepatitis (inflammation of the liver)
- a complex side-effect, which may include some or all of the following symptoms: fever, inflammation of the blood vessels often with skin rash, muscle pain and inflammation, joint pain and inflammation, abnormal blood test results, blood disorders, rash, sensitivity to light, other skin conditions and serositis (inflammation of membranes lining the lungs, heart, stomach and some organs).

These are very serious but rare side effects. You may need urgent medical attention or hospitalisation.

The following side effects have been reported at the approximate frequencies shown:

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

- blurred vision
- dizziness
- cough
- nausea (feeling sick)
- lethargy.

Common (may affect up to 1 in 10 people):

- headache, depression
- low blood pressure (you may feel light-headed or faint), fainting
- chest pain, changes in heart/pulse rate including a fast heart rate
- shortness of breath
- diarrhoea, abdominal pain, changes in sense of taste
- rash
- tiredness
- allergic reactions with swelling of the face, extremities, lips, tongue, throat with difficulty swallowing or breathing
- change in some blood tests (increased potassium and creatinine level in blood).

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

- sudden fall in blood pressure (especially when standing up)
- low blood sugar levels or sodium levels, high level of blood urea, confusion, sleepiness, difficulty sleeping, nervousness, pins and needles and numbness, vertigo (a sensation that your surroundings are spinning, either up and down or from side to side)

- anaemia (low blood count causing unusual tiredness or weakness)
- heart attack, stroke (these are more common in high risk patients)
- palpitations (awareness of your heartbeat)
- runny nose, sore throat and hoarseness, wheezing
- inflammation of your pancreas (swollen painful abdomen), constipation, back pain and vomiting, indigestion, loss of appetite, dry mouth, stomach ulcer
- sweating, itching, nettle rash, hair loss
- kidney problems including kidney failure
- protein in the urine giving the urine a frothy appearance
- impotence (inability to get or maintain an erection)
- muscle cramps, flushing, ringing in the ears, general feeling of being unwell, fever.

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

- blood disorders (characterised by fever, chills, sore throat, ulcers in the mouth or throat or unexplained bruising or bleeding)
- bone marrow depression, swollen glands, autoimmune diseases (where the body attacks itself)
- erythema multiforme
- “Stevens-Johnson syndrome” (a serious skin condition with reddening, scaling of your skin, blistering or detachment of the top layer of skin)
- abnormal dreams and other sleep disturbances
- Raynaud’s phenomenon (poor blood circulation which makes the toes and fingers numb and pale)
- runny and itchy nose, pneumonia, pulmonary infiltrates
- inflammation and ulceration of the mouth and tongue
- higher levels of liver enzymes or bilirubin in blood,, liver failure, hepatitis (inflammation of the liver), jaundice (yellowing of the skin and whites of the eyes)
- blisters which may burst easily becoming raw and painful or may bleed, red itchy spots, peeling skin leaving red raw patches over the body, blisters/bleeding of the lips, eyes, nose, mouth and genitals
- breast swelling in men
- the production of a reduced amount of urine.

There have also been reports of a symptom complex which may include some or all of the following: Fever, inflammation of the blood vessels, muscle pain and inflammation, bone pain and inflammation, abnormal blood test results, blood disorders, rash, sensitivity to light and other skin conditions.

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

- swelling in your intestine (intestinal angioedema)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

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

5. How to store Enalapril Maleate

Keep this medicine out of the sight and reach of children.

Store in the original container. Do not store above 30°C.

Do not use this medicine after the expiry date which is stated on the outer packaging after EXP. The expiry date refers to the last day of that month.

Do not transfer them to another container. Keep them in a secure place where children cannot get at them.

This medicine is for you ONLY, do not give it to anyone else.

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 Maleate Tablets contain:

- The active substance is Enalapril Maleate, 5 mg, 10 mg, or 20 mg.
- The other ingredients are colloidal anhydrous silica, magnesium stearate, sodium hydroxide, povidone, talc, crospovidone, microcrystalline cellulose, lactose monohydrate.

What Enalapril Maleate Tablets look like and contents of the pack:

- The 5 mg tablets are white or almost white, round tablets engraved with ED 5 on one side and a breakline on the other side
 - The 10 mg tablets are white or almost white, round tablets engraved with ED 10 on one side and a breakline on the other side
 - The 20 mg tablets are white or almost white, round tablets engraved with ED 20 on one side and a breakline on the other side
 - The tablets are available in pack sizes of 28, 30, 50, 90, and 100 tablets.
 - The 5 mg tablets are also available in pack sizes of 10, 60, and 500 tablets.
 - The 20 mg tablets are also available in pack sizes of 14 and 500 tablets.
- Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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Manufacturer

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