

Package leaflet: Information for the user**ENALAPRIL MALEATE 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. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

Enalapril contains an active substance called enalapril maleate. This belongs to the group of medicines called ACE inhibitors (angiotensin converting enzyme inhibitors).

Enalapril is used:

- to treat high blood pressure (hypertension).
- to treat heart failure (weakening of heart function). It can lower the need to go to hospital and can help some patients live longer.
- to prevent the signs of heart failure. The signs include: shortness of breath, tiredness after light physical activity such as walking or swelling of the ankles and feet.

Enalapril works by widening your blood vessels. This lowers your blood pressure. The medicine usually starts to work within an hour, and the effect lasts for at least 24 hours. Some people will require several weeks of treatment until the best effect on your blood pressure is seen.

2. What you need to know before you take Enalapril**Do not take Enalapril if:**

- you are allergic to enalapril maleate or any of the other ingredients of this medicine (listed in Section 6).

- you have ever had an allergic reaction to a type of medicine similar to Enalapril called an ACE inhibitor.
- you have ever had swelling of your face, lips, mouth, tongue or throat which caused difficulty in swallowing or breathing (angioedema) when the reason why was not known or it was inherited.
- you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.
- you are more than 3 months pregnant (it is better to avoid Enalapril in early pregnancy-see pregnancy section).
- if you are being treated with sacubitril/valsartan, a medicine for 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 if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Enalapril.

Warnings and precautions

Talk to your doctor or pharmacist before taking Enalapril if you:

- have a heart problem.
- have a condition involving the blood vessels in the brain.
- have a blood problem such as low or lack of white blood cells (neutropenia/agranulocytosis), low blood platelet count (thrombocytopenia) or a decreased number of red blood cells (anaemia).
- have a liver problem.
- have a kidney problem (including kidney transplantation), are on a salt-restricted diet, are taking potassium supplements, potassium sparing agents, or potassium containing salt substitutes, or other drugs that may increase potassium in your blood (e.g., heparin [a medicine used to prevent blood clots], trimethoprim-containing products such as cotrimoxazole [medicines used to treat infections]) These may lead to higher levels of potassium in your blood which can be serious. Your doctor may need to adjust your dose of Enalapril or monitor your blood level of potassium. See also information under the heading “Other medicines and Enalapril”.
- are having dialysis.
- have been very sick (excessive vomiting) or had bad diarrhoea recently.
- are over 70 years of age.
- have diabetes. 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.
- have ever 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.
- have low blood pressure (you may notice this as faintness or dizziness, especially when standing).

- have collagen vascular disease (e.g. 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.
- are breast-feeding or about to start breast-feeding (see Breastfeeding section).
- are taking any of the following medicines, the risk of angioedema may be increased:
 - Racecadotril, a medicine used to treat diarrhoea.
 - Medicines used to prevent organ transplant rejection and for cancer (e.g., temsirolimus, sirolimus, everolimus).
 - Vildagliptin, a medicine used to treat diabetes.
- 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”)

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

You should be aware that Enalapril lowers the blood pressure in black patients less effectively than in non-black patients.

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

If you are about to have a procedure

If you are about to have any of the following, tell your doctor that you are taking Enalapril:

- any surgery or receive anaesthetics (even at the dentist).
- a treatment to remove cholesterol from your blood called ‘LDL apheresis’.
- a desensitisation treatment, to lower the effect of an allergy to bee or wasp stings.

If any of the above apply to you, talk to your doctor or dentist before the procedure

Other medicines and Enalapril

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes herbal medicines. This is because enalapril

can affect the way some medicines work. Also some other medicines can affect the way enalapril works. Your doctor may need to change your dose and/or to take other precautions.

In particular tell your doctor or pharmacist if you are taking any of the following medicines:

- an angiotensin II receptor blocker (ARB) or aliskiren (see also information under the headings ‘Do not take Enalapril’ and ‘Warnings and precautions’)
- other medicines to lower blood pressure, such as beta-blockers or water tablets (diuretics)
- 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 infection caused by bacteria; ciclosporin, an immunosuppressant medicine used to prevent organ transplant rejection; and heparin, a medicine used to thin blood to prevent clots). See also information under the heading “Warnings and precautions”
- medicines for diabetes (including oral antidiabetic medicines and insulin)
- lithium (a medicine used to treat a certain kind of depression)
- medicines for depression called ‘tricyclic antidepressants’
- medicines for mental problems called ‘antipsychotics’
- certain cough and cold medicines and weight reducing medicines which contain something called a ‘sympathomimetic agent’
- certain pain or arthritis medicines including gold therapy
- non-steroidal anti-inflammatory drugs, including COX-2 inhibitors (medicines that reduce inflammation, and can be used to help relieve pain)
- aspirin (acetylsalicylic acid).
- medicines used to dissolve blood clots (thrombolytics).
- an mTOR inhibitor (e.g. temsirolimus, sirolimus, everolimus; medicines used to treat certain type of cancer or to prevent the body’s immune system from rejecting a transplanted organ). See also information under the heading “Warning and precautions”.
- a medicine containing a neprilysin inhibitor such as sacubitril (available as fixed-dose combination with valsartan), racecadotril or vildagliptin. The risk of angioedema (swelling of the face, lips, tongue or throat with difficulty in swallowing or breathing) may be increased. See also information under the headings “Do not take Enalapril” and “Warnings and precautions”.
- medicines used to dissolve blood clots (thrombolytics)
- alcohol

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

Enalapril with food, drink and alcohol

Enalapril can be taken with or without food. Most people take Enalapril with a drink of water. Alcohol can increase the effect of this medicine.

Check with your doctor or pharmacist before drinking any alcohol.

Pregnancy, breast-feeding and fertility**Pregnancy**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. Your doctor will normally advise you to stop taking Enalapril before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Enalapril. Enalapril 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 breastfeeding. Breast-feeding newborn babies (first few weeks after birth), and especially premature babies, is not recommended whilst taking Enalapril. In the case of an older baby your doctor should advise you on the benefits and risks of taking Enalapril while breast-feeding, compared to other treatments.

Driving and using machines

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

Enalapril tablets contain lactose.

If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product.

Information on sodium content

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium free’.

3. How to take Enalapril

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

- It is very important to continue taking Enalapril for as long as your doctor prescribes it.
- Do not take more tablets than prescribed.

High Blood Pressure

- The recommended starting dose ranges from 5 to 20 mg taken once a day.
- Some patients may need a lower starting dose.
- The recommended 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 recommended 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 recommended 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.

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.

Children

Experience in the use of Enalapril 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 recommended 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.

Enalapril is not recommended in newborn babies (first few weeks after birth) and in children with kidney problems. Tablet can be divided into equal doses.

If you take more Enalapril than you should

If you take more Enalapril than you should, talk to your doctor or go to a hospital straight away. Take the medicine pack with you. The following effects may happen: feeling of light-headedness or dizziness. This is due to a sudden or excessive drop in blood pressure.

If you forget to take Enalapril

- If you forgot 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

Do not stop taking your medicine, unless your doctor has told you to. If you do your blood pressure may increase. If your blood pressure becomes too high it may affect your heart and kidneys.

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.

The following side effects may happen with this medicine:

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

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

Uncommon (may affect up to 1 in 100 people)

- 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).
- ringing in your ears (tinnitus), inflammation of your pancreas (sudden severe abdominal pain, nausea, vomiting).

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

- bone marrow depression - signs of sudden sore throat, mouth ulcers, tiredness, unexplained bruising and bleeding.
- pneumonia (inflammation of the lungs causing difficulty breathing).
- rash that looks like targets (erythema multiforme)
- ‘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).
- liver or gall bladder problems such as lower liver function, inflammation of your liver, jaundice (yellowing of the skin or eyes), higher levels of liver enzymes or bilirubin (measured in a blood test).

You should be aware that black patients are at increased risk of these types of reactions. If any of the above happen, stop taking Enalapril and talk to a doctor straight away.

When you start taking Enalapril you may feel faint or dizzy. If this happens, it will

help to lie down. This is caused by your blood pressure lowering. It should improve as you continue to take the medicine. If you are worried, please talk to your doctor.

Other possible side effects

- **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)

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

Uncommon (may affect up to 1 in 100 people)

- sudden fall in blood pressure.
- fast or uneven heart beats (palpitations).
- confusion, sleeplessness or sleepiness, nervousness.
- feeling your skin prickling or being numb, vertigo (spinning sensation).
- runny nose, sore throat or hoarseness, asthma -associated tightness in chest
- slow movement of food through your intestine (ileus).
- being sick (vomiting), indigestion, constipation, anorexia.
- irritated stomach (gastric irritations), dry mouth, ulcer
- impaired kidney function, kidney failure
- increased perspiration.
- itching or nettle rash, loss of hair.
- muscle cramps, flushing, generally feeling unwell (malaise), high temperature (fever), impotence.
- high level of proteins in your urine (measured in a test).
- low level of blood sugar or sodium, high level of blood urea (all measured in a blood test) anaemia (including aplastic and haemolytic).

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

- ‘Raynaud’s phenomenon’ where your hands and feet may become very cold and white due to low blood flow.
- changes in blood values such as a lower number of white and red blood cells, lower haemoglobin, lower number of blood platelets.
- swollen glands in neck, armpit or groin
- autoimmune diseases, strange dreams or sleep problems.
- inflammation of your nose, accumulation of fluid or other substances in the lungs (as seen on X-rays)

- inflammation of the cheeks, gums, tongue, lips, throat.
- lower amount of urine produced.
- enlargement of the mammary glands in males.

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

- swelling in your intestine (intestinal angioedema).

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

- Syndrome of inappropriate antidiuretic hormone secretion (SIADH) overproduction of antidiuretic hormone, which causes fluid retention, resulting in weakness, tiredness or confusion
- A symptom complex has been reported 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) eosinophilia, and leucocytosis. Rash, photosensitivity or other dermatologic manifestations may occur.
- Psoriasis and psoriasisiform dermatitis

Reporting of side effects

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. You can also report side effects directly via the Yellow Card Scheme website: 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

- Keep this medicine out of sight and reach of children.
- Do not use this medicine after the expiry date (Exp) which is stated on the carton or blister. The expiry date refers to the last day of that month.
- Do not store above 25°C. Store in the original package.
- 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 Enalapril maleate Tablets contain**

- Each tablet contains 10 mg or 20 mg of Enalapril maleate as the active ingredient.
- The other ingredients are lactose monohydrate, maleic acid, hypromellose, croscarmellose sodium, sodium stearyl fumarate.

What Enalapril maleate tablets look like and contents of the pack

- Enalapril maleate 10 mg tablets are white to off-white, round, flat, bevelled edged, tablets with “BL” on one side and break line and 10 debossed on the other side.
- These tablets are available in blister packs containing 28, 49 x 1, 30, 50, 98 or 100 tablets.
- Enalapril maleate 20 mg tablets are white to off-white, round, flat, bevelled edged, tablets with “BL” on one side and break line and 20 debossed on the other side.
- These tablets are available in blister packs containing 10, 14, 20, 28, 28 x 1, 30, 49 x 1, 50, 56, 60, 84, 90, 98, 100 or 500 tablets.
- Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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Enalapril maleate 20 mg Tablets; PL 17907/0268

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