

ENALAPRIL MALEATE TABLETS 2.5mg ENALAPRIL MALEATE TABLETS 5mg ENALAPRIL MALEATE TABLETS 10mg ENALAPRIL MALEATE TABLETS 20mg

(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:

1. What ENALAPRIL MALEATE TABLETS are and what they are used for
2. What you need to know before you take ENALAPRIL MALEATE TABLETS
3. How to take ENALAPRIL MALEATE TABLETS
4. Possible side effects
 5. How to store ENALAPRIL MALEATE TABLETS
 6. Contents of the pack and other information

1. WHAT ENALAPRIL MALEATE TABLETS ARE AND WHAT THEY ARE USED FOR

ENALAPRIL MALEATE TABLETS (referred to as 'ENALAPRIL' throughout this leaflet) contains the active substance enalapril maleate.



'ENALAPRIL' belongs to a group of medicines known as ACE inhibitors (Angiotensin Converting Enzyme Inhibitors). 'ENALAPRIL' works by causing your blood vessels to widen. This helps your blood pressure to fall. It also makes it easier for your heart to pump blood around your body.

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 their blood pressure is seen.

'ENALAPRIL' is used:

- To treat high blood pressure – also called 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.

2. What you need to know before you take 'ENALAPRIL' Do not take 'ENALAPRIL' if:

- You are allergic to enalapril maleate, any other ACE inhibitors (type of medicines similar to 'ENALAPRIL') or any of the other ingredients of this medicine (listed in section 6).
- Any member of your family has had an allergic reaction to these medicines or you have ever had swelling of your face, eyelids, 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 also better to avoid 'ENALAPRIL' in early pregnancy - see pregnancy section).
- 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' if any of the above applies to you. If you are not sure about taking 'ENALAPRIL', talk to your doctor.

Warnings and precautions

Talk to your doctor or pharmacist before taking 'ENALAPRIL' if:

- You have low blood pressure (you may notice this as faintness or dizziness, especially when standing).
- You have a condition involving the blood vessels in the brain.
- You have a heart problem.
- You have a kidney problem (including kidney transplantation), are on a salt-restricted diet, are taking potassium supplements, potassium-sparing agents, 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".
- You have a liver problem.
- You 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).
- You have ever had an allergic reaction, 'angioneurotic oedema' or 'angioedema'. The signs include itching, red marks on the hands, feet and throat, swelling of the face, around the eyes, 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.

- You are having dialysis.
- You have been very sick (excessive vomiting) or had bad diarrhoea recently.
- You 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.
- You 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.
- You 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, 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 if"

You must tell your doctor if you think you are (or might become) pregnant. This medicine 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 applies 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 desensitization treatment, to lower the effect of an allergy to bee or wasp stings.

If any of the above applies 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, including medicines obtained without a prescription. 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:

- Potassium supplements (including salt substitutes), potassium sparing diuretics such as spironolactone, triamterene or amiloride 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 blood clots). See also information under the heading "warnings and precautions".
- Other medicines to lower blood pressure, such as beta-blockers, water tablets (diuretics) such as thiazides, furosemide, bumetanide, or medicines for chest pain (angina) such as nitroglycerine. Taking 'ENALAPRIL' at the same time may cause low blood pressure.
- an angiotensin II receptor blocker (ARB) or aliskiren (see also information under the headings "Do not take ENALAPRIL if" and "Warnings and precautions")
- Lithium (for some types of mental illness)
- Medicines for depression called 'Tricyclic antidepressants', medicines for serious mental illness called 'antipsychotics', anaesthetics or narcotics such as morphine (for severe pain). Taking these medicines at the same time as 'ENALAPRIL' may cause low blood pressure.
- Medicines used for stiffness and inflammation associated with painful conditions, particularly those affecting your muscles, bones and joints:
 - non-steroidal anti-inflammatory drugs, including COX-2-inhibitors (medicines that reduce inflammation, and can be used to help relieve pain)
 - gold therapy can lead to flushing of your face, feeling sick (nausea), vomiting and low blood pressure, when taken with 'ENALAPRIL'.
- An mTOR inhibitor (e.g., temsirolimus, sirolimus, everolimus; medicines used to treat certain types of cancer or to prevent the body's immune system from rejecting a transplanted organ). See also information under the heading "Warnings 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 if" and "Warnings and precautions".
- Aspirin (acetylsalicylic acid).
- Medicines used to dissolve blood clots (thrombolytics).
- Certain cough and cold medicines and weight reducing medicines which contain something called a 'sympathomimetic agent'.
- Medicines for diabetes (including oral antidiabetic medicines and insulin). 'ENALAPRIL' may cause your blood sugar levels to drop even further when taken with these medicines. This is more likely to occur during the first weeks of taking 'ENALAPRIL' and in patients with kidney problems. You should check your blood sugar level closely during the first month of taking 'ENALAPRIL'
- Alcohol

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

If you are going to have an anaesthetic (for an operation), tell your doctor or dentist that you are taking 'ENALAPRIL'.

'ENALAPRIL' with food, drink and alcohol

- You can take 'ENALAPRIL' with or without food.
- If you drink alcohol while taking 'ENALAPRIL' it may cause your blood pressure to drop too much and you may feel dizzy, light-headed or faint. Take care with the amount of alcohol you drink.

Pregnancy and Breast-feeding

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 breast-feeding. 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' whilst breast-feeding, compared to other treatments.

Driving and using machines: 'ENALAPRIL' may make you feel tired or dizzy. If this happens, do not drive or use any tools or machines.

'ENALAPRIL' contains lactose: Lactose is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

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 has told you. Check with your doctor or pharmacist if you are not sure. The dose of 'ENALAPRIL' will depend on the condition being treated and any other medicines you are taking.

Taking 'ENALAPRIL' tablets

- Swallow the tablets with water. You can take them with or without food.
- Take your tablet at about the same time each day. Take the 'ENALAPRIL' tablet marked for the correct day on the blister pack. This will help you remember whether you have taken it.

The first 'ENALAPRIL' tablets you take may make your

blood pressure fall by more than doses you take after that. The first tablets may make you feel dizzy or light-headed. It may help to lie down until you feel better. This effect becomes less likely with future doses. If you are concerned, talk to your doctor or pharmacist.

The doctor will check how you respond to taking 'ENALAPRIL' by taking your blood pressure and doing some blood tests.

Adults with high blood pressure (hypertension)

- The initial dose is 5 mg per day up to 20 mg taken once a day depending on your blood pressure.
 - Some patients may need a lower starting dose.
 - The usual long-term dose is 20 mg taken once a day.
 - The maximum daily dose is 40mg taken once a day.
- The actual dose, decided by your doctor, will depend on your blood pressure and other medical conditions. If you are taking a high dose of water tablets (diuretics), your doctor may ask you to stop taking them for 2 to 3 days before you start taking 'ENALAPRIL'.

Adults with heart failure

- The starting dose is usually 2.5mg 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 maximum daily dose is 40 mg, split into two doses of 20mg.

People with kidney problems

- If you have kidney problems, the doctor will alter the amount of 'ENALAPRIL' you take depending on how well your kidneys are working.
- If you are on kidney dialysis your dosage may vary day by day. Your doctor will let you know what your dose should be.

Elderly patients

- Your dose will be decided by your doctor. It will depend on how well your kidneys are working.

Use in children

- Experience in the use of 'ENALAPRIL' in children with high blood pressure is limited.
- If the child can swallow tablets the dose will depend on the child's weight and how their blood pressure changes after taking 'ENALAPRIL'. The doctor will decide on the dose
- Children with kidney problems are not recommended to take 'ENALAPRIL'
- Very young babies (first few weeks after birth) are not recommended to take 'ENALAPRIL'

The score line is only there to help you break the tablet if you have difficulty swallowing it whole.

If you take more 'ENALAPRIL' than you should

Contact your doctor or go to the nearest hospital casualty department straight away. Remember to take with you any remaining tablets and the pack, so the doctor knows what you have taken.

The most common signs and symptoms of overdose are fall in blood pressure and stupor (a state of almost complete lack of consciousness). Other symptoms may include dizziness or lightheadedness due to a fall in blood pressure, forceful and rapid heartbeat, rapid pulse, anxiety, cough, kidney failure, and rapid breathing.

If you forget to take 'ENALAPRIL': If you miss a dose do not worry. Take your normal dose when it is next due. Do not take a double dose to make up for a forgotten tablet.

If you stop taking 'ENALAPRIL': If you stop taking your medication, your blood pressure may increase. If your blood pressure becomes too high it may affect the function of your heart and kidneys. Do not stop taking your medicine, unless your doctor has advised you to do so.

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 see a doctor or go to a hospital straight away if:

- You begin to itch, develop a raised red skin rash (hives), get short of breath or wheezy and develop swelling of the hands, feet or ankles, face, eyes, mouth, lips, tongue or throat, which may cause difficulty in breathing or swallowing.

This may mean you are having an allergic reaction to 'ENALAPRIL'.

You should be aware that black patients are at increased risk of these types of reactions.

- You get rash which looks like targets, blisters, skin peeling off in sheets, which may appear also on the lips, eyes, mouth, nose and/or genitals. You may also have a high temperature or joint pain (erythema multiforme).
- You get severe skin reaction of which symptoms may be reddening of the skin, skin scaling, blistering or raw sores, detachment of the top layer of the skin from bottom layers ('Steven-Johnson Syndrome', 'toxic epidermal necrolysis').
- A bloating feeling and cramping pain in the abdomen (may be caused by an obstruction of the gut)
 - Heart attack or stroke possibly due to excessive low blood pressure in high-risk patients (patients with blood flow disturbances to the heart or brain)
 - Severe abdominal pain (may be caused by inflammation of the pancreas)
 - Blood disorders which affect the cells or elements in the blood and are usually diagnosed by blood tests (symptoms may be tiredness, weakness, shortness of breath, inability to exercise, feeling run down, having constant or re-occurring colds, fever, chills, prolonged bleeding, bruising where cause is unknown, red or purple spots)
 - Fluid on the lung which causes symptoms such as cough, difficulty breathing
 - High temperature, tiredness, loss of appetite, stomach pain, feeling sick, jaundice (yellowing of the skin or eyes) and liver failure. These are symptoms of Hepatitis (inflammation of the liver) or bile duct obstruction (stoppage of bile flow from the bile duct in the liver).

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.

Talk to your doctor straight away if you notice any of the following serious side-effects.

A complex side effect has also been reported which may include some or all of the following signs:

- Fever, inflammation of your blood vessels, pain and inflammation of muscles or joints
- Blood disorders affecting the components of your blood (usually detected by a blood test)
- Rash, hypersensitivity to sunlight and other effects on your skin.

Other side effects include:

Very common: may affect more than 1 in 10 people

- blurred vision
- dizziness
- cough
- feeling sick (nausea)
- weakness

Common: may affect up to 1 in 10 people

- headache
- depression
- low blood pressure which may cause light-headedness
- Fainting (syncope)
- heart rhythm changes
- fast heart beat
- chest pain or angina pectoris
- difficulty breathing
- diarrhoea
- pain around your stomach area (abdominal pain)

- change in sense of taste
- rash
- tiredness (fatigue)
- allergic reaction with swelling of the face, lips, tongue or throat with difficulty in swallowing or breathing
- 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

- tiredness and low haemoglobin or red blood cell count (anaemia).
- low blood sugar levels that may cause anxiety, a sense of heightened awareness or a shaky feeling.
- low level of sodium, high level of blood urea (all measured in a blood test)
- sudden fall in blood pressure
- confusion
- sleepy or unable to sleep
- nervousness
- tingling or pins and needles like sensation in the skin, feeling your skin prickling or being numb
- vertigo (spinning sensation)
- rapid forceful or uneven heart beats (palpitations)
- runny nose
- sore throat and hoarseness
- coughing and/or wheezing and/or breathing difficulties (asthma)
- slow movement of food through your intestine, inflammation of the pancreas, which causes symptoms such as severe pain in the abdomen and back.
- feeling sick (vomiting), indigestion, constipation, loss of appetite
- stomach irritation, dry mouth, peptic ulcer (symptoms may be burning, aching pain with an empty feeling and hunger, particularly when the stomach is empty).
- excessive sweating
- itching
- nettle-rash or hives
- hair loss
- reduced kidney function or kidney failure (symptoms may be lower back pain and reduction in the volume of urine passed)
- high level of proteins in the urine, which is usually detected by a blood test.
- difficulty getting an erection (impotence)
- muscle cramps
- flushing
- ringing in the ears (tinnitus)
- fever
- generally feeling unwell
- low blood pressure (which may make you feel dizzy when you stand up)
- 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)

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

- abnormal dreams, sleep disorders.
- small arteries, usually in the fingers and toes, go into spasm causing the skin to become pale or patchy red to blue colour and very cold-('Raynaud's phenomenon')
- changes in blood values such as a lower number of white and red blood cells, lower haemoglobin, lower number of blood platelets.
- pulmonary infiltrates (accumulation of fluid or other substances in the lungs, as seen on X-rays), pneumonia (signs may be cough, high temperature and difficulty breathing).
- inflammation of your nose
- pain, inflammation and/or ulceration of the gums, cheeks, tongue, lips, throat.
- liver or gallbladder problems such as lower liver function, inflammation of the liver which may cause yellowing of the skin or eyes (jaundice), higher levels of liver enzymes or bilirubin (measured in a blood test).
- reduction in the amount of urine produced per day
- enlargement of breasts in men
- Bone marrow depression
- Autoimmune diseases
- Exfoliative dermatitis/erythroderma (severe skin rash with flaking or peeling of the skin), pemphigus (small fluid-filled bumps on the skin)
- Swollen glands in neck, armpit or groin.

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

- swelling in your intestine (intestinal 'angioedema'). Signs may include stomach pain, feeling sick, vomiting.

Not known: frequency cannot be estimated from the available data

- 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). 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 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.

Blood tests: Taking 'ENALAPRIL' may affect the results of some blood tests. These include tests on: the blood cells or other parts of it, potassium levels, creatinine or urea, sodium, liver enzymes or bilirubin.

If you are going to have a blood test, it is important to tell your doctor that you are taking 'ENALAPRIL'.

5. How to store 'ENALAPRIL'

- keep this medicine out of the sight and reach of children.
- store in the original package
- do not store above 25°C
- 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' contains

The active substance is enalapril maleate
Each tablet contains 2.5mg, 5mg, 10mg or 20mg of enalapril maleate.

The other ingredients are lactose monohydrate, maize starch, sodium bicarbonate, pregelatinised maize starch, and magnesium stearate. The 10 mg and 20 mg tablets also contain iron oxide (E172).

What 'ENALAPRIL' looks like and contents of the pack
ENALAPRIL MALEATE TABLETS 2.5mg and ENALAPRIL MALEATE TABLETS 5mg are white, round, biconvex tablets, bisected on one side. The 2.5mg tablets are of smaller size than the 5mg tablets.
ENALAPRIL MALEATE TABLETS 10mg and ENALAPRIL MALEATE TABLETS 20mg are pink, round, biconvex tablets, quadrisectioned on one side. The 10mg tablets are of smaller size than the 20mg tablets.

All strengths of tablets are available in packs of 28 tablets in foil blister strips.

Marketing Authorisation Holder and Manufacturer

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This leaflet was last revised in: October 2021



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