

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, please ask your doctor or your 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.

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 more than 3 months pregnant. (it is also better to avoid 'ENALAPRIL' in early pregnancy - see pregnancy section).
- You are allergic (hypersensitive) to enalapril maleate, any other ACE inhibitors (type of medicines similar to 'ENALAPRIL'), or any of the other ingredients in these tablets (see Section 6: Further Information).
- 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. Do not take 'ENALAPRIL' if any of the above apply to you. If you are not sure about taking 'ENALAPRIL', talk to your doctor.

Warnings and precautions

Talk to your doctor 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 narrowed heart valve (mitral valve stenosis) or aorta (aortic stenosis), or have a heart problem known as 'hypertrophic cardiomyopathy'. These all cause the blood to flow less freely away from the heart
- You have kidney disease, including narrowed blood vessels in your kidneys (renal artery stenosis) or recently had a kidney transplant. 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.
- 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 type of reactions to ACE inhibitors.
- You are a dialysis patient, are taking diuretics (water tablets), are on a salt restriction diet, or have suffered from excessive vomiting or diarrhoea
- 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 take extra potassium in your diet or a salt substitute that contains potassium
- 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 are over 70 years of age.
- 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 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 desensitization 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, 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.

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

- Medicines containing potassium (including dietary salt substitutes).
- Water tablets (potassium sparing diuretics) such as spironolactone, eplerenone, triamterene or amiloride. Taking 'ENALAPRIL' at the same time may increase the levels of potassium in your blood.
- Other water tablets (diuretics) such as thiazides, furosemide, bumetanide or other medicines to lower your blood pressure such as beta-blockers, medicines for chest pain (angina) such as nitroglycerine. Taking 'ENALAPRIL' at the same time may cause low blood pressure.
- Lithium (for some types of mental illness)
- Medicines for depression called 'Tricyclic antidepressants', medicines for serious mental illness called 'anti psychotics'; 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 which can lead to flushing of your face, feeling sick (nausea), vomiting and low blood pressure, when taken with 'ENALAPRIL'.
- 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 apply 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

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

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 maximum daily dose is 40mg, 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.

Older people

- 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'

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 red, swollen skin, 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, swollen glands 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.

Below is a list of side effects that have occurred in patients taking 'ENALAPRIL'.

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
- Fainting (syncope)
- heart rhythm changes

- fast heart beat
- chest pain (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 person in 100):

- 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.
- confusion
- sleepy or unable to sleep
- nervousness
- tingling or pins and needles like sensation in the skin
- vertigo (spinning sensation)
- rapid forceful or uneven heart beats
- 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.
- being 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)
- presence of protein in the urine, which is usually detected by a test.
- difficulty getting an erection (impotence)
- muscle cramps
- flushing
- ringing in the ears
- 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)
- Low level of blood sodium, high level of blood urea (all measured in a blood test).

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-('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, 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 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

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.

If you get any side effects, talk to your doctor.

This includes any possible side effects not listed in this leaflet.

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 shown on the pack.
- 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 10mg and 20mg 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, quadrisected 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.

The Marketing Authorisation Holder/The Manufacturer is: Dexcel®-Pharma Ltd., 7 Sopwith Way, Drayton Fields, Daventry, Northamptonshire NN11 8PB, UK.

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