

120 mm

**PACKAGE LEAFLET: INFORMATION FOR THE USER**

**ENALAPRIL 5 mg, 10 mg & 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).

**THIS LEAFLET CONTAINS**

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
5. How to store Enalapril
6. Contents of the pack and other information

**1. WHAT ENALAPRIL IS AND WHAT IT IS USED FOR**

Enalapril belongs to a group of medicines known as angiotensin-converting enzyme inhibitors (ACE inhibitors). It works by causing your blood vessels to relax, making it easier for your heart to pump blood around your body.

Enalapril can be used to treat:

- high blood pressure (hypertension)
- heart failure, where the heart has difficulty pumping blood around the body

Enalapril can also:

- slow down the development of the symptoms of heart failure, which include shortness of breath, swelling of the ankles and feet, and tiredness after only light activity
- slow down the progress of heart failure
- reduce the need for hospitalisation in patients with heart failure or unstable angina
- reduce the risk of heart attacks occurring in patients with unstable angina

If you are not sure why you have been prescribed Enalapril, please ask your doctor.

**2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ENALAPRIL**

**Do not take Enalapril:**

- if you are allergic (hypersensitive) to enalapril, other ACE inhibitors (such as captopril, lisinopril or ramapril), or any of the other ingredients of Enalapril Tablets (see section 6). The symptoms of an allergic reaction may include itching, rash, swelling of the hands, feet, face, lips, tongue or throat which may cause difficulty swallowing or breathing.
- if you or any member of your family have ever suffered from swelling of the face, lips, tongue or throat, which may have made it difficult to swallow or breathe, (angioedema)
- if you have diabetes or kidney problems and are taking a medicine containing alicikren to reduce blood pressure
- if you are more than 3 months pregnant, (it is also best to avoid Enalapril in early pregnancy – see section 'Pregnancy and breast-feeding')
- 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 this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist.

**Warnings and precautions**

Talk to your doctor before you taking Enalapril:

- if you are at increased risk of developing low blood pressure (hypotension), which may cause dizziness, light-headedness or fainting. It is more likely to occur if you:
  - are being treated with medicines to increase urine production (diuretics)
  - have been told to limit the amount of salt in your diet
  - are having kidney dialysis
  - have recently suffered from severe diarrhoea or vomiting
- if you have a narrowing (stenosis) of the heart valve or aorta, or have a thickening of the heart muscle (hypertrophic cardiomyopathy)
- if you have a kidney problem, including narrowing of the blood vessels supplying your kidneys (renal artery stenosis), or high blood pressure due to a blocked blood vessel in the kidney (renovascular hypertension), or have recently had a kidney transplant
- if you have a liver problem
- if you have a blood problem such as altered numbers of white blood cells, red blood cells or blood platelets. This may cause symptoms including unexplained bleeding, bruising, increased infections, sore throat, fever, weakness, breathlessness, pale skin or general illness. A blood test can be taken to check.
- if you are having treatment to reduce your body's reaction to bee and wasp stings (hymenoptera desensitisation)
- if you are having treatment by a machine to remove cholesterol from your blood (LDL apheresis)
- if you have diabetes. You should closely monitor your blood for low blood sugar levels (hypoglycaemia), especially during the first month of treatment.
- if you have high levels of potassium in the blood (hyperkalaemia), which may cause palpitations or abnormal heart rhythm. This is more likely to occur if you:
  - have or are developing kidney problems
  - are aged 70 years or over
  - suffer from diabetes

- are dehydrated
- have an increased level of acid in your body (metabolic acidosis)
- are being treated with potassium-sparing diuretics (e.g. spironolactone, eplerenone, triamterene, or amiloride)
- are taking potassium supplements or potassium containing salt substitutes
- are taking other medicines associated with increases in blood potassium (e.g. heparin)
- If you are taking any of the following medicines, the risk of angioedema (rapid swelling under the skin in area such as the throat) is increased:
  - sirolimus, everolimus and other medicines belonging to the class of mTOR inhibitors (used to avoid rejection of transplanted organs)

People of a Black African or Caribbean origin need to be aware that, in this group of patients:

- allergic reactions to Enalapril are more common
- Enalapril may not work as well as it does in patients of other backgrounds

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 section 'Pregnancy and breast-feeding')

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

**Other medicines and Enalapril**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines bought without a prescription. This is because Enalapril can affect the way some medicines work, and some medicines can affect the way that Enalapril works.

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

- other medicines to treat high blood pressure and heart problems, such as alpha-blockers (e.g. doxazosin, prazosin), adrenergic neurone blocking agents (e.g. guanethidine), angiotensin-II receptor antagonists (e.g. candesartan, irbesartan, losartan), beta blockers (e.g. atenolol, propranolol), calcium channel blockers (e.g. amlodipine, nifedipine), nitrates (e.g. glyceryl trinitrate, isosorbide mononitrate), alicikren, clonidine, diazoxide, hydralazine, methylodopa, minoxidil, moxiblyte, moxonidine, sodium nitroprusside
- medicines to increase urine production (diuretics), such as amiloride, bendroflumethiazide, indapamide, furosemide, spironolactone
- medicines to treat mental health problems, such as chlorpromazine, haloperidol, lithium, olanzapine, risperidone
- medicines to treat depression, such as amitriptyline, dosulepin, imipramine
- medicines to treat diabetes, such as insulin, gliclazide, metformin
- non-steroidal anti-inflammatory drugs (NSAIDs), including those known as COX-2 inhibitors, for pain and inflammation such as aspirin, ibuprofen, indometacin, celecoxib, parecoxib
- medicines used to thin the blood and stop blood clots from forming, such as warfarin, heparin
- medicines known as sympathomimetics, such as bambuterol, fenoterol, salbutamol or terbutaline, used to treat asthma
- steroids, such as hydrocortisone or prednisolone, to treat swelling and allergies
- azathioprine or ciclosporin to suppress the immune system and stop the rejection of organs after transplants
- aldesleukin to treat cancer
- allopurinol to treat gout
- gold therapy, such as sodium aurothiomalate, for rheumatoid arthritis
- medicines or supplements containing potassium (including salt substitutes)
- 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'.
- if 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
- if 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": 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"

**Enalapril with food and drink**

The absorption of Enalapril is not affected by food intake, and so these tablets can be taken with or without food.

You should avoid alcohol whilst taking Enalapril, as it can increase the risk of the side effects.

**Pregnancy and breast-feeding**

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

30 mm

510 mm

50 mm

12 mm

8 mm

30 mm

120 mm

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.

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 breastfeeding, compared with other treatments.

**Driving and using machines**

While taking Enalapril you may experience dizziness, blurred vision, muscle cramps or weakness. If this happens, do not drive or operate machinery, tell your doctor.

**Operations and Tests**

If you are going to have a surgical operation or any procedure requiring you to receive an anaesthetic, tell your doctor or dentist that you are taking Enalapril.

Taking Enalapril may affect the results of some clinical tests. If you are going to have a test, it is important to tell your doctor or nurse that you are taking Enalapril.

Your doctor may want you to have blood tests to check your blood cells and liver function before you start taking the tablets and at regular intervals during your treatment.

**Enalapril contains lactose**

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

**3. HOW TO TAKE ENALAPRIL**

Always take this medicine exactly as your doctor has told you to. The dose of Enalapril will vary from person to person, and depend on the condition being treated. Your doctor will decide on the most appropriate dose for you. Check with your doctor or pharmacist if you are not sure.

You should take your dose at the same time each day unless your doctor tells you otherwise. If you are taking two doses a day, take one in the morning and one in the evening, unless your doctor has told you otherwise.

**Adults**

**For high blood pressure:**

The starting dose is usually 5 - 20 mg once a day, but may be less than 5 mg once a day in some patients. The typical maintenance dose is 20 mg once daily. The maximum maintenance dose is 40 mg once daily.

**For heart failure:**

The starting dose is usually 2.5 mg once daily. Your doctor may gradually increase the dose to the usual maintenance dose of 20 mg a day, as either a single dose or two divided doses. The maximum maintenance dose is 40 mg daily, divided into two doses.

**Patients with kidney problems:**

If you have kidney problems your doctor may adjust your dose, depending on how well your kidneys are working. If you are having dialysis, your dose may be changed on the non-dialysis days depending on your blood pressure.

**Elderly**

Your doctor will decide on the best dose for you based on how well your kidneys are working.

**Children**

Experience of the use of Enalapril in children with high blood pressure is limited.

For children who can swallow tablets, your doctor will work out the dose depending on the child's weight and blood pressure.

Enalapril is not recommended in newborn babies or children with kidney problems.

**If you take more Enalapril than you should**

If you take more tablets than you should, contact your doctor or go to the nearest hospital casualty department immediately. Take this leaflet and the medicine pack with you, so the doctor knows what has been taken.

**If you forget to take Enalapril**

If you forget to take a dose, take it as soon as you remember. However, if it is nearly time for your next dose, skip the missed dose and take your next scheduled dose at the correct time. Do not take a double dose to make up for a forgotten dose.

**If you stop taking Enalapril**

Even if you feel better, do not stop taking the tablets, as your condition may get worse. You should take your medicine until your doctor tells you to stop.

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.

**If you get any of the following side effects, STOP TAKING Enalapril and tell your doctor or go to the nearest hospital emergency department immediately:**

- allergic reaction, the symptoms of which may include itching, rash, swelling of the hands, feet, face, lips, tongue or throat which can cause difficulty swallowing or breathing
- severe skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis), appearing initially as reddish target-like spots or circular patches often with central blisters. The rash may progress to widespread blistering or peeling of the skin
- heart attack or stroke

**If you get any of the following serious side effects, stop taking Enalapril and tell your doctor as soon as possible:**

- inflammation of the pancreas (pancreatitis) which can cause severe stomach pain that reaches through to your back
- inflammation of the liver (hepatitis), which causes yellowing of the skin or whites of the eyes (jaundice), liver damage or failure
- changes to your blood such as altered numbers of white blood cells, red blood cells or blood platelets. This may cause symptoms including unexplained bleeding or bruising, increased risk of infections, sore throat, fever, weakness,

breathlessness, pale skin or general illness. A blood test can be taken to check.

- an obstruction or blockage of the bowel, which may cause a bloating feeling and cramping pain in the stomach area

**Tell your doctor or pharmacist if you get any of the following side effects:**

**Very common side effects (may affect more than 1 in 10 people)**

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

**Common side effects (may affect up to 1 in 10 people)**

- low blood pressure (hypotension, which may cause light-headedness on standing up), fainting, chest pain, tightness in the chest (angina), fast or uneven heartbeats
- diarrhoea, abdominal pain, changed sense of taste
- headache, depression
- shortness of breath
- tiredness (fatigue)
- increased levels of potassium in the blood, increased levels of creatinine in the blood (detected by blood tests)

**Uncommon side effects (may affect up to 1 in 100 people)**

- low levels of red blood cells, (anaemia), which can make your skin pale and cause tiredness and breathlessness
- low blood sugar levels (hypoglycaemia), which may make you feel a sense of nervousness, shaky or sweaty
- palpitations
- vomiting, indigestion, constipation, loss of appetite, stomach irritations, dry mouth, peptic ulcer the symptoms of which may include a burning, aching pain with an empty feeling and hunger
- confusion, sleepiness, sleeplessness, nervousness, tingling or numbness ('pins and needles'), a feeling of dizziness or "spinning" (vertigo)
- difficulty in breathing, wheezing, asthma, runny nose, sore throat and hoarseness
- excessive sweating, itchiness, hives rash, hair loss
- impaired kidney function, kidney failure, protein in the urine
- difficulty getting or maintaining an erection (impotence)
- muscle cramps, flushing, ringing in the ears, feeling uncomfortable or unwell, fever
- increased urea in the blood, low levels of sodium in the blood (shown in blood tests)

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

- swollen lymph nodes, autoimmune diseases – when the immune system mistakenly attacks healthy cells
- poor blood circulation which causes discolouration and numbness in the fingers and toes (Raynaud's phenomenon)
- inflammation or ulceration of the lining of the mouth, inflammation of the tongue
- abnormal dreams, sleep disorders
- swelling and irritation inside the nose
- lung problems caused by substances, such as mucus, blood or dust, in the lungs, the signs of which include fever, cough and difficulty breathing
- low urine output
- development of breasts in men
- increased levels of liver enzymes, increased levels of blood bilirubin (detected by blood tests)

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

- swelling of the intestines, symptoms may include stomach pain, nausea or vomiting

**Other possible side effects**

- excessive release of antidiuretic hormone resulting in the blood sodium levels become low, which can cause tiredness, confusion, muscle twitching, fits, coma

**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](http://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 the sight and reach of children.**

Do not use this medicine after the expiry date which is stated on the blister strip and carton. 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 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 (the ingredient that makes the tablets work) is enalapril maleate. Each tablet contains either 5, 10 or 20 mg of enalapril maleate.

The other ingredients are lactose monohydrate; maize starch and glycerol distearate.

**What Enalapril look like and contents of the pack**

Enalapril Tablets are white circular and uncoated, with either '5', '10' or '20' embossed on one face and a score line on the other.

Enalapril 5 mg, 10 mg and 20 mg Tablets are available in the blister packs of 28.

**Marketing Authorisation Holder**

RIA Generics Limited  
36 Ingleby Way, Wallington, Surrey, SM6 9LR, United Kingdom

**Manufacturer**

RIA Generics Limited  
36 Ingleby Way, Wallington, Surrey, SM6 9LR, United Kingdom

If you would like to have any further information or want to report any side effects, please email at [info@riagenerics.com](mailto:info@riagenerics.com).

**This leaflet was last revised in November 2021**

30 mm

511 mm

PP21EE/0021