

PACKAGE LEAFLET

Package leaflet: Information for the patient

Enalagen 2.5mg Tablets

Enalagen 5 mg Tablets

Enalagen 10 mg Tablets

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

1. What Enalagen is and what it is used for

The tablets contain enalapril maleate. Enalapril maleate belongs to a group of medicines known as ACE inhibitors, which work by widening your blood vessels. The effect of these medicines is to lower your blood pressure.

- Enalagen is used to treat high blood pressure (hypertension).
- It is also used to treat a heart condition sometimes referred to as 'heart failure'. This means that your heart is not working as well as it used to, in order to pump blood around your body, leading to tiredness after light physical activity, breathlessness and swelling of your ankles and feet. Enalagen may help treat these symptoms.
- In many patients with a damaged heart muscle, but who have no symptoms, Enalagen may help to prevent the appearance of symptoms such as shortness of breath and swelling.
- Enalagen should only be used in children for high blood pressure (hypertension).

2. What you need to know before you take Enalagen

Do not take Enalagen

- if you are more than 3 months pregnant. (It is also better to avoid enalapril maleate in early pregnancy – see pregnancy section.)
- if you are allergic to enalapril maleate, similar medicines known as ACE inhibitors or any of the other ingredients of this medicine (listed in section 6). Signs of an allergic reaction may have been itching, nettle rash, wheezing or swelling of your hands, throat, mouth or eyelids.

- if 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 if a member of your family has a history of suffering from angioedema.
- 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.
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.

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

Warnings and Precautions

Talk to your doctor or pharmacist before taking Enalagen if:

- you have kidney problems, such as ‘renal artery stenosis’ (reduced blood flow to the kidney), have had a recent kidney transplant, are a dialysis patient, or are taking water tablets (diuretics)
- you have low levels of sodium in the blood, are on a salt restricted diet, have suffered from excessive vomiting or diarrhoea recently or are dehydrated
- you have a heart condition called ‘ischaemic heart disease’ which reduces the blood supply to the heart muscles, which may cause chest pain (angina)
- you have a heart condition called ‘aortic stenosis’, ‘hypertrophic cardiomyopathy’ or ‘outflow obstruction’
- you have a condition affecting the blood supply to your brain (‘cerebrovascular disease’) e.g. you have had a stroke or mini-stroke (also known as a ‘TIA’)
- you have collagen vascular disease, are taking immunosuppressant therapy (used for the treatment of autoimmune disorders such as rheumatoid arthritis or following transplant surgery)
- you are taking allopurinol, (used for the treatment of gout), or procainamide, (used to treat abnormal heart rhythms)
- you have a history of ‘angioedema’ while taking other medicines. The signs may have been itching, nettle rash, wheezing or swelling of your hands, throat, mouth or eyelids. You should be aware that Afro-Caribbean patients are at an increased risk of these types of reactions to ACE inhibitors
- you have diabetes and are taking antidiabetic medicines, including insulin to control your diabetes (you should monitor your blood for low blood glucose levels, especially during the first month of treatment)
- 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.
- you are taking potassium supplements or potassium containing salt substitutes
- you are over 70 years old or have too much acid in the blood (metabolic acidosis).
- you are taking other medicines that can affect the level of potassium in your blood, such as heparin (an anticoagulant)
- you are taking lithium, used for the treatment of some mental health conditions
- you have had surgery on the airways (e.g. lungs)
- you think you are (or might become) pregnant. Enalagen 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).

Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals.

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:

- racecadotril, a medicine used to treat diarrhoea
- medicines used to prevent organ transplant rejection and to treat cancer (e.g. temsirolimus, sirolimus, everolimus).
- vildagliptin, a medicine used to treat diabetes.

See also information under the heading “Do not take Enalagen”

You should be aware that this medicine may be less effective at lowering the blood pressure in Afro-Caribbean patients than in non-Afro-Caribbean patients.

While taking Enalagen

If you develop any of the following symptoms you should let your doctor know immediately:

- jaundice (yellowing of the skin and whites of the eyes)
- a dry cough which is persistent for a long time.
- a high temperature, sore throat or mouth ulcers (these may be symptoms of infection caused by the lowering of the number of white blood cells).

If you are about to have any of the following procedures, you should tell your doctor who is treating you that you are taking Enalagen:

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

Routine tests

When you first start to take enalapril maleate, your doctor will monitor your blood pressure frequently to ensure you have been given the correct dose. In addition, for some patients the doctor may want to do some tests to measure your potassium, creatinine, liver enzyme levels and blood cell count.

Children and adolescents

Information on the use of enalapril maleate in children over 6 years old who have high blood pressure is limited, but for children with heart problems there is no information. Enalapril maleate should not be used in babies or children with reduced kidney function.

Other medicines and Enalagen

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription as some drugs may affect each other's action. This includes herbal medicines. Also some other medicines can affect the way enalapril maleate works:

- 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).
- water tablets (diuretics) such as thiazides *e.g.* bendroflumethiazide, furosemide or bumetanide as these may cause a severe drop in blood pressure when the first doses are taken.
- other medicines that lower blood pressure, such as angiotensin receptor blockers (*e.g.* losartan and valsartan), nitroglycerin, nitrates, and vasodilators as these may increase the effect of enalapril maleate.
- heparin, co-trimoxazole also known as trimethoprim/sulfamethoxazole or other medicines that increase the level of potassium in your blood.
- lithium, used for the treatment of some mental health conditions. Enalapril maleate should not be taken with this medicine as it may increase the levels of lithium in the blood.
- 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”.
- tricyclic antidepressants such as amitriptyline, used for depression, antipsychotics such as phenothiazines, used for severe anxiety and mental health conditions as these can increase the effects of enalapril maleate.

- pain killers such as morphine, because your blood pressure may become too low.
- medicines used for stiffness and inflammation associated with painful conditions, particularly those affecting your muscles, bones and joints:
 - including gold therapy which can lead to flushing of your face, feeling sick (nausea), vomiting and low blood pressure, when taken with enalapril maleate, and
 - non-steroidal anti-inflammatory drugs (NSAIDs) including COX-2 inhibitors, for example diflunisal or diclofenac. They may prevent your blood pressure from being well controlled and may increase the level of potassium in your blood
- medicines such as ephedrine, used in some cough and cold remedies, or noradrenaline and adrenaline used for low blood pressure, shock, cardiac failure, asthma or allergies. If used with enalapril maleate these medicines may keep your blood pressure high
- Allopurinol (used to treat gout) or procainamide (used to treat abnormal heart rhythms) as these may increase the risk of developing low levels of white blood cells in your body.
- antidiabetic medicines such as insulin. Enalagen may cause your blood sugar levels to drop even further if you take it with antidiabetics.

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 Enalagen” and “Warnings and precautions”).

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

Enalagen with alcohol

If you drink alcohol while taking Enalagen, it may cause your blood pressure to drop too much and you may experience dizziness, light-headedness or faintness. You should keep your alcohol intake to a minimum.

Pregnancy

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

If you are breast-feeding or about to start breast-feeding, ask your doctor or pharmacist for advice before taking this medicine. 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

Certain side effects, such as dizziness and weariness, have been reported with enalapril maleate, which may affect some patients' ability to drive or operate machinery.

Enalagen contains lactose monohydrate and sodium

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 Enalagen

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

Taking this medicine

- You should take this medicine by mouth.
- The number of tablets you take each day will depend upon your condition.
- Enalapril maleate can be taken with or without food.

The score line is only there to help you break the tablet if you have difficulty swallowing it whole and not to divide it into equal doses.

Dosage for high blood pressure

The initial recommended dose is 5 mg per day up to 20 mg per day depending on your blood pressure. In patients with blood pressure levels slightly above normal the recommended dose is 5-10 mg per day. For patients with kidney problems, heart problems, low salt and or fluid levels a starting dose of 5 mg or lower should be used.

If you are currently taking high dose diuretics (water tablets), your doctor may ask you to stop taking them 2-3 days prior to taking Enalagen. A starting dose of 5 mg or lower is recommended.

Once your blood pressure is under control, the recommended maintenance is 20 mg daily up to a maximum of 40 mg daily.

Dosage for heart disorders

In patients with heart problems, enalapril maleate is used in addition to diuretics and where appropriate, with digitalis (a drug used in congestive heart failure or for an erratic heartbeat) or beta-blockers (drugs used to treat high blood pressure, angina and heart problems). The initial dose of 2.5 mg each day should be gradually increased, to the recommended maintenance dose of 20 mg given in a single dose or two divided doses, over a 2 to 4 week period. The maximum dose is 40 mg daily given in two divided doses.

Reduced kidney function

In patients with kidney problems, your dose of enalapril maleate will need to be adjusted depending on how well your kidneys are functioning. Kidney function is calculated by measuring the amount of creatinine (a waste product) in your urine and also by taking a blood test.

If you are having dialysis, your dosage will vary daily. Your doctor will let you know what your dose should be.

Older patients

Your dose will be decided by your doctor, and will be based on how well your kidneys are functioning.

Use in children and adolescents

Experience in the use of enalapril maleate in children with high blood pressure is limited. If the child can swallow tablets the dose will be determined based on the child's weight and blood pressure response. The recommended starting dose is 2.5 mg in children 20 kg to less than 50 kg and 5 mg in children 50 kg and over. Enalagen is given once daily. The dosage should be adjusted according to the needs of the child to a maximum of 20 mg daily in children 20 kg to less than 50 kg and 40 mg in children 50 kg and over.

Babies and children with kidney problems

Enalagen should not be used in babies or children with kidney problems.

If you take more Enalagen than you should

Contact your doctor immediately if you think you have taken more of your tablets than you should. The most common signs and symptoms of an overdose are a fall in blood pressure and stupor (a state of almost complete lack of consciousness). Other symptoms may include dizziness or light-headedness due to a fall in blood pressure, forceful, slow or rapid heartbeat, rapid pulse, anxiety, cough, kidney failure, and rapid breathing.

If you forget to take Enalagen

- If you forget 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 Enalagen

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 Enalagen immediately and go straight away to hospital or seek medical advice from your doctor if you get any of the following side effects:

Common (may affect up to 1 in 10 people)

- heavy or pressing sensation on your chest with chest pain and an increased shortness of breath on exercise (these may be signs of problems with your heart such as angina)
- allergic reaction- you may have difficulty breathing or wheeze, develop itchy red rashes, swelling of your hands, mouth, lips, tongue throat, face or eyes.

Uncommon (may affect up to 1 in 100 people)

- tiredness, shortness of breath, coldness in your hands and feet and pale skin, difficulty in healing after a cut (this may indicate you have a low number of red blood cells in the blood)
- sudden collapse, numbness or weakness in the arms or legs, headache, dizziness and confusion, disturbances in vision, difficulty swallowing, slurred, mixed up or loss of speech (these may be signs of a stroke caused by a clot or bleed affecting blood supply to part of the brain)
- sudden chest pain which may spread to the neck or arm, with a shortness of breath and a clammy feeling (these may be signs of a heart attack)
- persistent constipation with a swollen stomach and being sick (these may be signs of a blockage in your intestine)
- severe stomach pain which may radiate to your back (this may be signs of problems with your pancreas)
- burning, aching pain with an empty feeling and hunger, particularly when the stomach is empty (caused by a stomach ulcer)
- producing little or no urine, cloudy urine or blood in the urine, pain when passing urine or lower back pain (these may be signs of serious problems with your kidneys).

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

- an increase in the number of infections you get such as fever, severe chills, sore throat or mouth ulcers (this may indicate you have a low number of white blood cells in the blood)
- weakness, unexplained or abnormal bruising or bleeding or more frequent, potentially severe, infections (this may be signs of a severe reduction of all types of blood cells which may be due to bone marrow depression)
- autoimmune diseases where the immune system tries to attack normal, healthy, tissue
- yellowing of your skin or whites of your eyes, dark urine, pale stools, tiredness, fever, nausea, weakness, drowsiness and abdominal pain, with test results showing abnormal liver function (these may be signs of problems with your liver)excessive painful redness of your skin, large blisters, skin peeling off in sheets, bleeding of the lips, eyes or mouth accompanied by fever (these may indicate serious skin conditions such as Stevens-Johnson syndrome, pemphigus or toxic epidermal necrolysis)
- cough, high temperature and difficulty breathing these may be signs of eosinophilic pneumonia, inflamed lung or inflammation of the lung (alveolitis)).

Not known (cannot be estimated from the available data)

- a lower than normal level of sodium in the blood, which may make you feel weak and confused with aching of muscles or fluid retention. This may be due to inappropriate ADH secretion, a hormone that causes the body to retain water and dilute the blood, reducing the amount of sodium.

Other possible side effects:

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

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

Common (may affect up to 1 in 10 people)

- headache, depression
- light-headedness, especially when you stand up (a sign of low blood pressure), fainting
- chest pain, heart rhythm changes, fast heartbeat, shortness of breath
- diarrhoea, pain around your stomach area (abdomen), changes in taste, fluid retention (oedema), feeling tired
- increased blood potassium level, increases in serum creatinine (both are usually detected by a blood test).

Uncommon (may affect up to 1 in 100 people)

- anxiety, a sense of heightened awareness or a shaky feeling (caused by low blood sugar), confusion, feeling sleepy, difficulty sleeping, feeling nervous, tingling or numbness, feeling like you are spinning (vertigo)
- uneven heartbeats you may feel as a thumping in your chest
- runny nose, sore throat and hoarseness or asthma
- being sick, indigestion, constipation
- loss of appetite (anorexia), stomach irritation, dry mouth,
- excessive sweating, itching, hives (urticaria), hair loss, protein in your urine (usually detected by a urine test)
- impotence, muscle cramps, flushing, ringing in your ears, a general feeling of being unwell, high temperature
- increases in blood urea and decreases in blood sodium levels (usually detected by a blood test).

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

- swollen glands in the neck, armpit or groin
- strange dreams, sleeping problems
- low blood flow to your fingers and toes causing them to turn cold, white and painful (Raynaud's), fluid on your lungs, stuffy or sore nose
- pain, swelling or ulcers in your mouth, infection or pain and swelling of your tongue, redness of your skin or measles-like spots
- development of breasts in men
- increased liver enzymes or blood 'bilirubin' (usually detected by a blood test).

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

- intestinal 'angioedema'. Signs may include stomach pain, feeling sick and vomiting, elevated calcium level in blood.

Not known (cannot be estimated from the available data)

- Psoriasis or worsening of psoriasis (skin disease that causes red, itchy scaly patches, most commonly on the knees, elbows, trunk and scalp).

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.

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

5. How to store Enalagen

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

Do not store Enalagen above 25°C. Store in the original container.

Do not put them into another container as they might get mixed up.

Do not use this medicine after the expiry date, which is stated on the carton or bottle after “EXP”.

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 Enalagen contains

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

The other ingredients are sodium hydrogen carbonate, pregelatinised starch, maize starch, lactose monohydrate (see section 2, ‘Enalagen contains lactose monohydrate’) and magnesium stearate.

In addition, the 10 mg tablets contain iron oxide red (E172)

In addition, the 20 mg tablets contain iron oxide brown (E172)

What Enalagen looks like and contents of the pack

Enalagen 2.5 mg tablets are white, oval shaped with two sides that curve out, marked with “2.5” scoreline “G” on one side and scoreline on the other, approximately 8 mm long, 5 mm wide and 3 mm thick.

Enalagen 5 mg tablets are white, arc triangle shaped with two sides that curve out, marked with “5” over “G” on one side and scoreline on the other, approximately 9 mm long, 9 mm wide and 4 mm thick.

Enalagen 10 mg tablets are rusty red, arc triangle shaped with two sides that curve out, marked with “10” over “G” on one side and scoreline on the other, approximately 9 mm long, 9 mm wide and 4 mm thick.

Enalagen 20 mg tablets are peach, arc triangle shaped with two sides that curve out, marked with “20” over “G” on one side and scoreline on the other, approximately 9 mm long, 9 mm wide and 4 mm thick.

Enalagen tablets are supplied in the following pack sizes:

- Blister packs in cardboard outer carton containing 10, 11, 14, 20, 28, 30, 49, (49 x 1 blister), 50, 56, 60, 84, 90, 98, 100, 250, 500 tablets.
- Bottle packs with desiccant and tamper-evident cap containing 10, 11, 14, 20, 28, 30, 50, 56, 60, 84, 90, 100, 250, 500 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Mylan, Station Close, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom

Manufacturer

Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland
Generics [UK] Ltd, Station Close, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom

Mylan Hungary Kft., H-2900 Komárom, Mylan utca 1, Hungary

This leaflet was last revised in October 2025.