Package leaflet: Information for the patient

Enalaprilmaleaat 30 mg, tabletten
Enalaprilmaleaat 40 mg, tabletten
enalaprilmaleaat

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Enalapril maleate is and what it is used for

Enalapril maleate is used
- to reduce high blood pressure (hypertension)
- for insufficient pumping power of the heart with symptoms of disease (symptomatic heart failure)
- for insufficient pumping power of the heart (heart failure) before symptoms occur, to prevent the occurrence of these symptoms (such as breathlessness, swollen ankles and feet, and fatigue after slight exertion such as walking).

Enalapril maleate belongs to the ACE inhibitor (angiotensin conversion inhibitors) group of medicines. Enalapril blocks the formation of a blood pressure-increasing substance by the body. As a result, the pressure falls and/or the action of the heart improves.

2. What you need to know before you take Enalapril maleate

Do not take Enalapril maleate:
- if you are allergic to:
  - enalapril or any of the other ingredients of this medicine (listed in section 6)
  - other ACE-inhibitors.
- if you had sudden fluid accumulation in the skin and mucous membranes (e.g. throat or tongue), breathing difficulties and/or itching and rash, often as an allergic reaction (angioedema) during earlier use of an ACE inhibitor. You should not take Enalapril maleate if you had any of these reactions without a known cause or if it has been confirmed that you have a hereditary or other form of angioedema (fluid accumulation).
- 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 are more than 3 months pregnant. (It is also better to avoid Enalapril maleate in early pregnancy – see pregnancy section.)
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.

Warnings and precautions
Talk to your doctor or pharmacist before taking Enalapril maleate:

- if you are on a low-salt diet, are on dialysis, have diarrhoea or vomiting or being treated with water tablets your blood pressure can become too low
- if you have problems with the heart like:
  - heart failure (insufficient pumping power of the heart); your blood pressure can become too low. The risk of this is greater if you have severe heart failure (for which you are taking high dosages of loop diuretics, a certain group of water tablets), if you have too little sodium in the blood (hyponatraemia) or a reduced kidney function. The doctor will monitor you more frequently if necessary.
  - heart disease caused by a poor blood supply or if you have a condition involving the blood vessels in the brain; the doctor will set the dose carefully and will monitor you more frequently if necessary. Treatment should be carried out with special caution, because a very great fall in blood pressure could cause a heart attack or a stroke.
  - the heart valves of your left ventricle are narrowed, or other outflow obstructions from the left ventricle. In the event of shock caused by the heart and in the event of obstruction of the circulation, administration must be avoided.
  - if in your case too great a fall in blood pressure occurs; you should then be placed in a lying-down position and, if necessary, a doctor should be warned. This does not mean that the treatment must be stopped. After restoration of the blood volume and blood pressure the therapy may possibly be resumed.
- if you have problems with your kidneys like:
  - if you have a disturbance of kidney function; the dosage should be adjusted; your doctor will monitor you at regular intervals.
  - poor kidney function or heart failure; enalapril can temporarily worsen the disturbance of kidney function and kidney failure may occur. The doctor will adjust your dosage and monitor you more frequently if necessary.
  - if you have had a kidney transplant; Enalapril maleate is not recommended in such cases.
  - you are on dialysis and are dialysed with a so-called “high flux” membrane; your doctor may decide to use a different membrane or prescribe a different blood pressure-lowering medicine.
  - if you are being treated with water tablets (diuretics), in some patients Enalapril maleate can cause an increase in certain substances in the blood (the so-called urea and creatinine level); this can be a sign that you have a narrowing of one or both renal arteries (renal artery stenosis). Your doctor will lower the dosage or stop the diuretic treatment.
  - if you have raised blood pressure as a result of narrowing of the renal artery (renovascular hypertension) you have an increased risk of a severe fall in blood pressure and a reduced action of your kidneys. Therefore in this case the treatment should take place under strict medical supervision with low dosages and cautious dose increases.
- if you have problems with your liver like:
  - developing jaundice or an increase in the liver enzymes during use of Enalapril maleate; stop taking it and consult your doctor.
- if you have a certain vascular condition or are being treated with medicines that affect the immune system, medicine for gout (allopurinol) or medicine for disturbances of heart rhythm (procainamide), especially in combination with impaired kidney function; you may develop blood abnormalities accompanied by severe infections. Your doctor will check your blood more frequently.
- if, during treatment, you develop hypersensitivity reactions or sudden fluid accumulation in the skin and mucous membranes (e.g. throat or tongue), breathing difficulties and/or itching and rash, often as an allergic reaction (angioedema), consult your doctor. In the event of swelling of the tongue, throat or larynx, the airways may become blocked, especially if you have had an operation on the airways. In these cases treatment should take place immediately.
- if you have higher risk for angioedema like:
  - if you have a darker skin colour; you have a higher risk of sudden fluid accumulation in the skin and mucous membranes (e.g. throat or tongue), breathing difficulties and/or

itching and rash, often as an allergic reaction and in addition the effect of Enalapril maleate may be reduced.
- if, in the past, you have had sudden fluid accumulation in the skin and mucous membranes (e.g. throat or tongue), breathing difficulties and/or itching and rash, often as an allergic reaction the risk of this recurring is greater.
- 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 for cancer (e.g. temsirolimus, sirolimus, everolimus and other medicines belonging to the class of mTOR inhibitors) and vildagliptin (a medicine used to treat diabetes).

- if you are being made insensitive to venom from e.g. bee or wasp stings; in rare cases you may develop a hypersensitivity reaction. These can be prevented by interrupting the Enalapril maleate treatment in good time.
- if you are undergoing treatment in which cholesterol is removed from your blood (LDL apheresis); you may develop a dangerous hypersensitivity reaction.
- if you are diabetics you should pay attention carefully to sign of a hypoglycaemia (blood glucose lowering) like weakness, sweating or thirst, in particular in first month of treatment with Enalapril maleate because the blood glucose-lowering effect can be strengthened.
- if you have too much potassium in the blood, your potassium values should be supervised during the treatment. Risk factors for raised potassium values include a reduced kidney function, age (> 70 years), diabetes (diabetes mellitus), intercurrent events in particular dehydration (fluid depletion), acute cardiac decompensation (a heart failure in which the heart is unable to circulate the blood properly, marked by labored breathing and edema), metabolic acidosis (disturbance in the body's acid-base balance with signs are rapid breathing, confusion and tiredness) and concurrent taking of potassium sparing water tablet (diuretic), a potassium supplement or potassium-containing salt substitutes or taking medicines that increase the concentration of potassium in the blood.
- if you are being treated with lithium; using lithium and Enalapril maleate at the same time is not recommended. However, if the combination is necessary, the lithium level in the blood must be closely monitored (please see also section 2. Taking other medicines).
- if you are taking any of the following medicines used to treat high blood pressure:
  - an angiotensin II receptor blocker (ARBs) (also known as sartans - for example valsartan, telmisartan, irbesartan), in particular if you have diabetes-related kidney problems.
  - aliskiren.

  Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals.
  See also information under the heading “Do not take Enalapril maleate”.
- if you are breast-feeding; the use of Enalapril maleate is not recommended;
- if you develop a dry persistent cough during treatment with Enalapril maleate, consult your doctor. The cough often disappears after the discontinuation of treatment.
- if you are undergoing major surgery or having anesthesia with agents that produce a very low blood pressure; your blood pressure can become too low

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

Children and adolescents
Except for use in raised blood pressure, there are no data on the use of Enalapril maleate in children and adolescents; use in children and adolescents is therefore not recommended unless enalapril is being used for raised blood pressure.

Other medicines and Enalapril maleate
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Enalapril maleate and other medicines can influence each other's effect and side effects.

- The following medicines increase the blood pressure lowering effect
  - water tablets (diuretics), other blood pressure-lowering medicines and vessel-dilatating medicines;
  - anaesthetics/anaesthesia, certain medicines for depression and medicines for severe mental disorder;
- Medicines with a stimulant effect on a certain part of the nervous system reduce the blood pressure lowering and/or diuretic effect
- It may be necessary to monitor/adjust dosage of blood sugar-lowering medicines; concomitant use with Enalapril maleate can potentiate the effect of these medicines
- Potassium supplements (including salt substitutes), potassium-sparing diuretics such as spironolactone, eplerenone, triamterene or amiloride, and other medicines that can increase the amount of potassium in your blood (e.g. trimethoprim and co-trimoxazole also known as trimethoprim/sulfamethoxazole 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). Mild hyperkalaemia causes few, if any symptoms and is usually diagnosed by a blood test or on an electrocardiogram. Use of these type of medicines in patients with kidney problems may lead to a significant increase in potassium in the blood with can cause serious side effects.
- 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".
- Non-steroidal anti-inflammatory drugs (NSAIDs), including acetylsalicylic acid at higher doses (for relieving pain and reducing fever) and COX-2-inhibitors (medicines that reduce inflammation, and can be used to help relieve pain) can reduce the effect of Enalapril maleate. Concomitant use with Enalapril maleate can also cause kidney problems. If necessary, the doctor may check a kidney function regularly during treatment with Enalapril maleate, especially in elderly and persons who are dehydrated, including those who are taking water tablets. Patients should drink sufficient amounts of liquid while taking this medicine.
- When taking lithium (medicine against depression), the concentration of lithium in the blood can increase and increase the risk of toxic effects of lithium developing.
- Sodium aurothiomalat, a medicine to injection against rheumatic arthritis

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 Enalapril maleate" and "Warnings and precautions").

Enalapril maleate with alcohol
Drinking alcohol together with this medicine can increase the blood pressure-lowering effect (and can then cause dizziness on standing up, among other things).

Pregnancy and breast-feeding
Ask your doctor or pharmacist for advice before taking any medicine.

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 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
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 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
Enalapril maleate can cause side effects such as dizziness and fatigue. This may have a negative effect on your reaction capacity. You should be aware of this when you drive or operate machines.

Enalapril maleate contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Enalapril maleate contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Enalapril maleate

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

30 mg tablets:

Raised blood pressure (hypertension)
Starting dosage: 5* mg to a maximum of 20 mg enalapril maleate (20 mg = 2/3 tablet of Enalapril maleate 30 mg) once daily, depending on the degree of hypertension. In some patients a lower starting dosage may be necessary (< 5* mg).
Maintenance dosage 20 mg enalapril maleate (20 mg = 2/3 tablet of Enalapril maleate 30 mg) per day, up to a maximum dosage of 40 mg enalapril maleate (40 mg = 1 tablet of Enalapril maleate 30 mg + 1/3 tablet of Enalapril maleate 30 mg) per day.

Heart failure/particular disturbance of heart function (asymptomatic left ventricular dysfunction)
Days 1 to 3 the staring dose is 2.5* mg once daily.
Days 4 to 7 the dose is 5*mg in two divided doses.
If the treatment is well tolerated, the dosage is gradually increased over 2 to 4 weeks to the usual maintenance dosage of 20 mg enalapril maleate (20 mg = 2/3 tablet of Enalapril maleate 30 mg) (divided into 1 or 2 doses per day). The maximum dosage is 40 mg enalapril maleate (40 mg = 1 tablet of Enalapril maleate 30 mg + 1/3 tablet of Enalapril maleate 30 mg) per day, divided into two doses.

Blood pressure, kidney function and the potassium level in the blood should be checked by your doctor before and after the treatment with Enalapril maleate.

Reduced kidney function
Your doctor will generally decide to lengthen the time between the administrations of Enalapril maleate or to lower the dosage of Enalapril maleate.
Starting dosage: 2.5* mg -10 mg enalapril maleate (10 mg = 1/3 tablet Enalapril maleate 30 mg) per day.

Use in elderly patients
The dosage is dependent on your kidney function.

Use in children and adolescents
There are few data available on the use of Enalapril maleate in children and adolescents with raised blood pressure (hypertension).

Starting dosage:
- 2.5* mg once daily for children weighing 20 to 50 kg
- 5* mg once daily for children weighing 50 kg or more.

Maintenance dosage: The further dosage is adapted by the doctor up to a maximum dosage of

- 20 mg enalapril maleate (20 mg = 2/3 tablet Enalapril maleate 30 mg) once daily for children weighing 20 to 50 kg
- 40 mg enalapril maleate (40 mg = 1 tablet of Enalapril maleate 30 mg + 1/3 tablet Enalapril maleate) once daily for children weighing 50 kg or more.

Use of Enalapril maleate in newborn babies and children with reduced kidney function is not recommended, because no data are available.

*Tablets containing smaller amounts such as 2.5 mg or 5 mg of enalapril maleate are available.

40 mg tablets:

Raised blood pressure (hypertension)
Starting dosage: 5* mg to a maximum of 20 mg enalapril maleate (20 mg = ½ tablet Enalapril maleate 40 mg) once daily, depending on the degree of hypertension. In some patients a lower starting dosage may be necessary (< 5* mg).
Maintenance dosage: 20 mg enalapril maleate (20 mg = ½ tablet Enalapril maleate 40 mg) per day, up to a maximum dosage of 40 mg enalapril maleate per day.

Heart failure/particular disturbance of heart function (asymptomatic left ventricular dysfunction)
Days 1 to 3 the staring dose is 2.5* mg once daily.
Days 4 to 7 the dose is 5* mg in two divided doses.
If the treatment is well tolerated, the dosage is gradually increased over 2 to 4 weeks to the usual maintenance dosage of 20 mg enalapril maleate (20 mg = ½ tablet Enalapril maleate 40 mg) (divided into 1 or 2 doses per day). The maximum dosage is 40 mg enalapril maleate per day, divided into two doses.

Blood pressure, kidney function and the potassium level in the blood should be checked by your doctor before and after the treatment with Enalapril maleate.

Reduced kidney function
Your doctor will generally decide to lengthen the time between the administrations of Enalapril maleate or to lower the dosage of Enalapril maleate.
Starting dosage: 2.5* mg-10 mg enalapril maleate (10 mg = 1/4 tablet Enalapril maleate 40 mg) per day.

Use in elderly patients
The dosage is dependent on your kidney function.

Use in children and adolescents
There are few data available on the use of Enalapril maleate in children and adolescents with raised blood pressure (hypertension).

Starting dosage:
- 2.5* mg once daily for children weighing 20 to 50 kg
- 5* mg once daily for children weighing 50 kg or more.

Maintenance dosage: The further dosage is adapted by the doctor up to a maximum dosage of
- 20 mg enalapril maleate (20 mg = ½ tablet Enalapril maleate 40 mg) once daily for children weighing 20 to 50 kg
- 40 mg enalapril maleate once daily for children weighing 50 kg or more.

Use of Enalapril maleate in newborn babies and children with reduced kidney function is not recommended, because no data are available.

*Tablets containing smaller amounts such as 2.5 mg or 5 mg of enalapril maleate are available.

How to take the tablet

Take the tablets or part-tablets with plenty of water before, during or after a meal.

Please store the tablet parts after dividing the tablet in a dry place protected from light and moisture.

If you notice that the effect of Enalapril maleate is too strong or even too weak, ask your doctor or pharmacist for advice.

If you take more Enalapril maleate than you should
If you have taken more Enalapril maleate than you should, contact your doctor or pharmacist immediately.

Symptoms of overdose can be: a feeling of light-headedness or dizziness because your blood pressure is falling, inability to move (stupor), shock, disturbance of the balance of dissolved salts in the blood or body (electrolyte balance), reduced action of the kidneys, hyperventilation, accelerated heart beat (tachycardia), palpitations, slow heart beat (bradycardia), dizziness, anxiety, cough.

If you forget to take Enalapril maleate
- If you have forgotten to take a dose, you can take it when you remember unless it is almost time for your next dose. In that case follow your usual schedule.
- Do not take a double dose to make up for a forgotten dose.

If you stop taking Enalapril maleate
Your doctor will tell you how long you must take Enalapril maleate. Do not stop the treatment early, because otherwise the disorders will return.

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.

- **Stop taking this medicine** and seek medical attention if you begin to itch, develop a severe skin rash with blistering or peeling, get short of breath or wheezy, and develop swelling of the face, hands, feet, mouth, throat or eyes. You may be allergic to this medicine.
- **Tell your doctor** if you suffer from sore throats, mouth ulcers more frequent infections or fever.
- **Tell your doctor** if you notice yellowing of your skin or whites of your eyes or have abdominal (tummy) pain.

Other side effects include:
Tell your doctor if any of the following gets serious or lasts longer than a few days.

Very common: may affect more than 1 in 10 people
- blurred vision
- dizziness
- cough
- nausea
- feeling unusually tired (asthenia)

Common: may affect up to 1 in 10 people
- headache, depression
- dizziness and light-headedness due to low blood pressure (hypotension), including dizziness and fainting on standing up quickly from a sitting or lying position (orthostatic hypotension)
- sudden loss of consciousness (syncope)
- chest pain
- disturbances of heart rhythm

- painful feeling of tightness in the chest (angina pectoris)
- fast heart beat (tachycardia)
- breathlessness (dyspnoea)
- diarrhoea, abdominal pain, taste disturbance
- rash
- allergic reactions with swelling of the face, lips, tongue, throat, the cleft between the vocal cords (glottis) and/or the larynx with difficulty in swallowing or breathing, and swelling of the arms and legs
- tiredness (fatigue)
- too much potassium in the blood sometimes manifesting itself as muscle cramps, diarrhoea, nausea, dizziness, headache (hyperkalemia)
- increase in breakdown products in the blood serum (serum creatinine)

Uncommon: may affect up to 1 in 100 people
- anemia as a result of a shortage of red blood cells (aplastic) or as a result of breakdown of red blood cells (haemolytic)
- too low a sugar level in the blood accompanied by a feeling of hunger, sweating, dizziness, palpitations (hypoglycaemia)
- confusion, sleepiness, sleeplessness, nervousness, sensation of prickling, itching or tingling without there being any cause (paraesthesia), feeling like you are spinning (vertigo)
- sudden fall in blood pressure
- fast or uneven heart beats (palpitations)
- 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 (cerebrovascular accident), possibly due to very low blood pressure in high-risk patients
- runny nose (rhinorrhoea)
- sore throat and hoarseness
- feeling of tightness in the chest as a result of spasm of the muscles in the airways (bronchospasm), attacks of tightness in the chest as a result of spasm of the muscles and swelling of the mucous membrane in the airways, often accompanied by cough and bringing up of mucus ((bronchial) asthma)
- slow movement of food through your bowel (ileus)/inflammation of the pancreas accompanied by severe pain in the upper abdomen radiating out to the back, with nausea and vomiting (pancreatitis)
- vomiting
- disturbed digestion with, as symptoms, a feeling of fullness in the upper abdomen, pain in the stomach region, belching, nausea, vomiting, and heartburn (dyspepsia)
- constipation, lack of appetite, irritated stomach, dry mouth, stomach ulcers
- excessive sweating (diaphoresis)
- itching (pruritus)
- rash with severe itching and formation of blisters (urticaria)
- hair loss
- disorder in kidneys function
- failure of the kidneys
- too much protein in the urine (proteinuria)
- inability to have sexual intercourse (impotence)
- muscle cramps
- facial redness
- buzzing in the ears (tinnitus)
- generally feeling unwell (malaise)
- fever
- increase a particular substance (urea) in the blood
- too little sodium in the blood (hyponatraemia)

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

- a blood abnormality (shortage of white blood cells) accompanied by increased susceptibility to infections (neutropenia)
- reduction in red blood cells (reduced haemoglobin and haematocrit)
- a blood abnormality (blood platelet shortage) accompanied by bruises and a tendency to bleed (thrombocytopenia)
- A very serious blood abnormality (shortage of white blood cells) accompanied by a sudden high fever, severe sore throat and ulcers in the mouth (agranulocytosis). If you experience an infection with symptoms such as fever and serious deterioration of your general condition, or fever with local infection symptoms such as sore throat/pharynx/mouth or urinary problems you should see your doctor immediately.
- bone marrow dysfunction (bone marrow depression)
- reduction of all cells in the blood (pancytopenia)
- facial swelling and abnormalities of the lymph glands (lymphadenopathy)
- disease with breakdown of the patient's own tissue (auto-immune disease)
- abnormal dreams, sleep disturbances
- paleness of fingers or toes (Raynaud's syndrome)
- certain forms of pneumonia (lung infiltrates, allergic alveolitis/eosinophilic pneumonia)
- swelling and irritation inside the nose characterised by blocked nose, sneezing and discharge (rhinitis)
- mouth sores and inflammation (aphthae/stomatitis), inflammation of the tongue
- reduced action of the liver
- inflammation of the liver (hepatitis) accompanied by jaundice (yellowing of the skin or eyes), including death of the tissue (necrosis)
- disturbance or stoppage of bile secretion (cholestasis), including jaundice
- rash with red (weeping) irregular patches (erythema (exsudativum) multiforme)
- severe hypersensitivity reaction with (high) fever, red patches on the skin, joint pain and/or eye inflammation (Stevens-Johnson syndrome)
- skin inflammation accompanied by scaling of the skin (exfoliative dermatitis)
- severe, acute (hypersensitivity) reaction accompanied by fever and blisters on the skin/peeling of the skin (toxic epidermal necrolysis)
- fluid-filled blisters on the skin (pemphigus)
- very severe skin condition accompanied by redness, accumulation of fluid and scaling over the entire body (erythrodermia)
- reduced excretion of urine
- breast development in men
- increase in certain substances in the liver (liver enzymes)
- increase in red bile colorant (bilirubin) in the blood

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

- swelling in the bowel (intestinal angioedema)

Not known: frequency cannot be estimated from the available data

- overproduction of antidiuretic hormone which causes fluid retention, resulting in weakness, tiredness, confusion up to the cramp attack or coma
- A condition with a group of symptoms including fever, inflammation of serous tissues (coating e.g. abdominal organs) (serositis), inflammation of a blood vessel (vasculitis), muscle pain (myalgia) and muscle inflammation (myositis), pains in the joints (arthralgia) and inflammation of the joints (arthritis) and certain blood abnormalities (including positive antinuclear antibodies (ANA), increased blood sedimentation rate, increase in the number of white blood cells (eosinophilia and leukocytosis)). The skin may also be sensitive to light and a rash or other skin reactions 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 national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [nationally completed name]

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 and the carton after "EXP". The expiry date refers to the last day of that month.

Do not store above 30 °C. Store in the original package in order to protect from light and moisture.

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 [nationally completed name] contains

- The active substance is enalapril maleate.
- Each tablet contains 30 mg enalapril maleate.
  Each tablet contains 40 mg enalapril maleate.
- The other ingredients are: sodium hydrogen carbonate (E 500), lactose monohydrate, maize starch, talc (E 553b), magnesium stearate (E 470b), ferric oxide, red (E 172), ferric oxide hydrate, yellow (E 172).

What [nationally completed name] looks like and contents of the pack

[Nationally completed name] 30 mg tablets are oblong, convex, orange tablets with two breaking notches, both sides scored with markings 'EN 30'.

The tablet can be divided into three equal doses.

[Nationally completed name] 40 mg tablets are oblong, convex, orange tablets with three breaking notches, both sides scored with markings 'EN 40'.

The tablet can be divided into four equal doses.

NL/H/0924:
[Nationally completed name] 30 mg tablets: The tablets are packed in aluminium/aluminium blisters containing 20, 30, 50, 60 or 100 tablets.
[Nationally completed name] 40 mg tablets: The tablets are packed in aluminium/aluminium blisters containing 20, 30, 50, 60 or 100 tablets.

NL/H/0925:
[Nationally completed name] 30 mg tablets: The tablets are packed in aluminium/aluminium blisters containing 20, 30, 50 or 100 tablets.
[Nationally completed name] 40 mg tablets: The tablets are packed in aluminium/aluminium blisters containing 20, 30, 50 or 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Hexal AG
Industriestrasse 25
83607 Holzkirchen
Duitsland

Fabrikant:
Salutas Pharma GmbH
Otto-von-Guericke Allee 1
39179 Barleben
Duitsland

In het register ingeschreven onder:
RVG 34164 (30 mg)
RVG 34165 (40 mg).

This medicinal product is authorised in the Member States of the EEA under the following names

Nederland:	Enalaprilmaleaat 30 mg, tabletten
	Enalaprilmaleaat 40 mg, tabletten
Duitsland:	Enalapril – 1A Pharma 30 mg tabletten
	Enalapril – 1A Pharma 40 mg tabletten

Deze bijsluiter is voor het laatst goedgekeurd in augustus 2019.