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### **Package leaflet: Information for the patient**

**<Invented name> 2.5 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 <Invented name> is and what it is used for
2. What you need to know before you take <Invented name>
3. How to take <Invented name>
4. Possible side effects
5. How to store <Invented name>
6. Contents of the pack and other information

#### **1. What <Invented name> is and what it is used for**

<Invented name> contains an active substance called enalapril maleate. This belongs to the group of medicines called ACE inhibitors (angiotensin converting enzyme inhibitors).

<Invented name> is used:

- to treat high blood pressure (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.

This medicine works by widening your blood vessels. This lowers your blood pressure. 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 your blood pressure is seen.

#### **2. What you need to know before you take <Invented name>**

**Do not take <Invented name>**

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- if you are allergic to enalapril maleate or any of the other ingredients of this medicine (listed in section 6).
- if you have a history of an allergic reaction with swelling of the face, lips, tongue and/or pharynx associated with swallowing or breathing difficulties (angioedema) in connection with previous treatment with ACE inhibitors or if you or someone in your family has had a similar reaction with no known reason.
- if you are more than 3 months pregnant (it is also better to avoid <Invented name> 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.
- 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 before taking this medicine.

### **Warnings and precautions**

Talk to your doctor or pharmacist before taking <Invented name>:

- if you have a heart problem
- if you have a condition involving the blood vessels in the brain
- if you have a blood disorder 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)
- if you have kidney problem or you have undergone a kidney transplantation. These may lead to higher levels of potassium in your blood which can be serious. Your doctor may need to adjust your dose of <Invented name> or monitor your blood level of potassium.
- if you are currently on dialysis therapy
- if you are diabetic. 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.
- if you have ever had an allergic reaction with swelling of the face, lips, tongue or throat with difficulty in swallowing or breathing. You should be aware that black patients are at increased risk of these types of reactions to ACE inhibitors.
- if you have a liver problem
- if you have low blood pressure (you may notice this as faintness or dizziness, especially when standing)
- if 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 must tell your doctor if you think that you are (or might become) pregnant. <Invented name> is not recommended in early pregnancy, and must not be taken if you are more than 3months pregnant, as it may cause serious harm to your baby if used at that stage (see pregnancy section).
- 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:

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- racecadotril, a medicine used to treat diarrhoea;
- temsirolimus, sirolimus, everolimus and other medicines belonging to the class of mTOR inhibitors (used to avoid rejection of transplanted organs and for cancer);
- vildagliptin, a medicine used to treat diabetes.
- 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.

You should be aware that this medicine lowers the blood pressure in black patients less effectively than in non-black patients.

See also information under the heading “Do not take <Invented name>”.

Caution should be followed in the beginning of the therapy to prevent severe reduction in blood pressure. This is particularly important in patients over 70 years of age, in patients receiving treatment with diuretics or with potassium-sparing medicines, in patients on a strict low-salt diet, in patients with severe vomiting or diarrhoea or in case of a cardiac disease or a history of stroke.

#### **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 <Invented name>:

- any surgery or receive anaesthetics (even at the dentist).
- a treatment to remove cholesterol from your blood called ‘LDL apheresis’
- a desensitisation treatment, to lower the effect of an allergy to bee or wasp stings.
- If any of the above applies to you, talk to your doctor or dentist before the procedure.

#### **Children and adolescents**

<Invented name> should not be used in children.

#### **Other medicines and <Invented name>**

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

Certain medicines may alter the effects from <Invented name> or it may alter the effects from other medicines. In particular tell your doctor or pharmacist if you are taking any of the following medicines. Your doctor may need to change your dose and/or to take other precautions:

- an angiotensin II receptor blocker (ARB) or aliskiren (see also information under the headings “Do not take <Invented name>” and “Warnings and precautions”)
- other medicines to lower blood pressure, such as beta-blockers or water tablets (diuretics)
- 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

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- to prevent organ transplant rejection; and heparin, a medicine used to thin blood to prevent clots)
- lithium (a medicine used to treat a certain kind of depression)
- non-steroidal anti-inflammatory drugs, including COX-2-inhibitors (medicines that reduce inflammation, and can be used to help relieve pain)
- aspirin (acetylsalicylic acid)
- medicines used to dissolve blood clots (thrombolytics)
- antidepressants, antipsychotics, narcotics
- anaesthetics
- certain cough and cold medicines and weight reducing medicines which contain something called a 'sympathomimetic agent'
- antidiabetic medicines (e.g. sulfonylureas and biguanides) or insulin
- gold by injection for treatment of arthritis (sodium aurothiomalate)
- medicines which are most often used to avoid rejection of transplanted organs and for treatment of cancer (temsirolimus, sirolimus, everolimus and other medicines belonging to the class of mTOR inhibitors). See section "Warnings and precautions".
- sacubitril/valsartan (used to treat long-term heart failure).
- medicine used to treat diarrhoea (racecadotril). See section "Warnings and precautions".
- a medicine used to treat diabetes (vildagliptin). See section "Warnings and precautions".

#### **<Invented name> with food, drink and alcohol**

<Invented name> can be taken independently of meals, but should be taken with an adequate amount of water (approx. 1½ dl).

Alcohol enhances the blood pressure lowering effects of <Invented name>.

#### **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this 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 <Invented name> before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of <Invented name>. <Invented name> 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 <Invented name>. In the case of an older baby your doctor should advise you on the benefits and risks of taking <Invented name> whilst breast-feeding, compared to other treatments.

#### **Driving and using machines**

Treatment with <Invented name> may cause dizziness or weariness. This should be considered in situations such as driving and using machines.

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### **<Invented name> contains lactose and sodium**

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

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

### **3. How to take <Invented name>**

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

- It is very important to continue taking this medicine for as long as your doctor prescribes it.
- Do not take more tablets than prescribed.

The usual dose is:

#### *High blood pressure*

The usual starting dose is 5 to 20 mg taken once daily.

Some patients may need a lower starting dose.

The usual maintenance dose is 20 mg taken once daily.

The maximum maintenance dose is 40 mg taken once daily.

*Heart failure* The usual starting dose is 2.5 mg once daily.

The doctor gradually increases the dose until the correct dosage is achieved.

The normal maintenance dose is 20 mg daily (as a single dose or divided into 2 sub-doses).

The maximum dose is 40 mg daily given in two divided doses.

#### *Patients with kidney problems*

Your dose of medicine will be changed depending on how well your kidneys are working:

- moderate kidney problems – 5 mg to 10 mg each day
- severe kidney problems - 2.5 mg each day
- if you are having dialysis - 2.5 mg each day. On days you are not having dialysis, your dose may be changed depending on how low your blood pressure is.

#### *Elderly patients*

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

### **Use in children**

Experience in the use of <Invented name> in children with high blood pressure is limited. If the child can swallow tablets, the dose will be worked out using the child's weight and blood pressure. The usual starting doses are:

between 20 kg and 50 kg – 2.5 mg each day.

50 kg or more – 5 mg each day.

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The dose can be changed according to the needs of the child:

- a maximum of 20 mg daily can be used in children who are between 20 kg and 50 kg.
- a maximum of 40 mg daily can be used in children weighing 50 kg or more.

<Invented name> is not recommended in newborn babies (the first weeks after birth) and in children with kidney problems.

#### **If you take more <Invented name> than you should**

If you take more <Invented name> than you should, talk to your doctor or go to a hospital straight away. Take the medicine pack with you. The following effects may happen: feeling of light headedness or dizziness. This is due to a sudden or excessive drop in blood pressure.

#### **If you forget to take <Invented name>**

If you forget to take a tablet, skip the missed dose.  
Do not take a double dose to make up for a forgotten tablet.

#### **If you stop taking <Invented name>**

Do not stop taking your medicine unless your doctor tells you to.  
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.

<Invented name> may cause severe allergic reactions. Discontinue <Invented name> medication and contact your doctor immediately, if any of the following symptoms (angioedema) appear:

- swelling of the face, lips, tongue or throat which may cause difficulty in breathing
- swallowing difficulties
- swelling of your hands, feet or ankles
- if you develop a raised red skin rash (hives).

You should be aware that black patients are at increased risk of these types of reactions. If any of the above happen, stop taking <Invented name> and talk to a doctor straight away.

When you start taking this medicine 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.

Other side effects include:

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

- blurring of the vision
- feeling dizzy, weak or sick
- cough.

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

- headache, depression
- low blood pressure (standing abruptly up may cause feeling of dizziness), fainting, chest pain, constriction of blood vessels (angina pectoris), disturbed heart rhythm, rapid pulse
- difficulties breathing
- diarrhoea, stomach pain
- rash, hypersensitivity reactions, such as swelling of the face, arms, legs, lips, tongue, vocal cords and/or larynx
- tiredness (fatigue)
- high blood potassium concentrations, increased levels of creatinine in your blood (both are usually detected by a test).

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

- flushing
- 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 (possibly due to very low blood pressure in high-risk patients)
- anaemia (including aplastic and haemolytic)
- confusion, sleeplessness or sleepiness, nervousness
- feeling your skin prickling or being numb
- vertigo (spinning sensation)
- ringing in your ears (tinnitus)
- runny nose, sore throat or hoarseness
- asthma-associated tightness in chest
- slow movement of food through your intestine (ileus), inflammation of your pancreas
- being sick (vomiting), indigestion, constipation, anorexia
- irritated stomach (gastric irritations), dry mouth, ulcer
- muscle cramps
- impaired kidney function, kidney failure
- increased sweating
- itching or nettle rash
- hair loss
- generally feeling unwell (malaise), high temperature (fever)
- impotence
- high level of proteins in your urine (measured in a test)
- low blood sugar or sodium concentration, high level of blood urea (all measured in a blood test).

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

- 'Raynaud's phenomenon' where your hands and feet may become very cold and white due to low blood flow

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- changes in blood values such as a lower number of white and red blood cells, lower haemoglobin, lower number of blood platelets
- bone marrow depression
- swollen glands in neck, armpit or groin
- autoimmune diseases
- strange dreams or sleep problems
- accumulation of fluid or other substances in the lungs (as seen on X rays)
- inflammation of your nose
- inflammation of the lungs causing difficulty breathing (pneumonia)
- inflammation of the cheeks, gums, tongue, lips, throat
- reduced amount of urine
- rash that looks like targets (erythema multiforme)
- ‘Stevens-Johnson syndrome’ and ‘toxic epidermal necrolysis’ (serious skin conditions where you have reddening and scaling of your skin, blistering or raw sores), exfoliative dermatitis/erythroderma (severe skin rash with flaking or peeling of the skin), pemphigus (small fluid-filled bumps on the skin)
- liver or gallbladder problems such as lower liver function, inflammation of your liver, jaundice (yellowing of the skin or eyes), high levels of liver enzymes or bilirubin (measured in a blood test)
- enlargening of the breasts (gynaecomastia).

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

- swelling (oedema) of the intestines (intestinal angioedema).

**Not known** (frequency cannot be estimated from the available data)

- overproduction of antidiuretic hormone, which causes fluid retention, resulting in weakness, tiredness or confusion.

A symptom complex has been reported which may include some or all of the following: fever, inflammation of the blood vessels (serositis/vasculitis), muscle pain (myalgia/myositis), joint pain (arthralgia/arthritis). Rash, photosensitivity or other skin manifestations may occur.

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the 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 <Invented 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 package after “EXP:”. The expiry date refers to the last day of that month.

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Store below 30°C. Store in the original package in order to protect from 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 <Invented name> contains**

- The active substance is enalapril maleate. Each tablet contains 2.5 mg enalapril maleate.
- The other ingredients are sodium hydrogen carbonate, lactose monohydrate, maize starch, talc, hydroxypropylcellulose and magnesium stearate. See section 2 "<Invented name> contains lactose and sodium".

### **What <Invented name> looks like and contents of the pack**

Tablet appearance:

Round, white, tablet with bevelled edges and a diameter of 6 mm.

Pack sizes:

Blister (Polyamide/Alu/PVC/Alu): 28, 30, 50, 60, 98, 100 or 100x1 tablets

Not all pack sizes may be marketed.

### **Marketing Authorization Holder and Manufacturer**

[To be completed nationally]

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

[To be completed nationally]

**This leaflet was last revised in:** 2019-06-27

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