



## PACKAGE LEAFLET: INFORMATION FOR THE USER

### Enalapril maleate 2.5mg Tablets Enalapril maleate 5mg Tablets Enalapril maleate 10mg Tablets Enalapril maleate 20mg Tablets (Enalapril maleate)

#### Read all of this leaflet carefully before you start taking this medicine.

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

### 1. WHAT ENALAPRIL MALEATE TABLETS ARE AND WHAT THEY ARE USED FOR

Enalapril maleate belongs to the class of medicines called Angiotensin converting enzyme inhibitors (ACE inhibitors). It works by causing blood vessels to relax, lowering blood pressure and increasing the supply of blood and oxygen to the heart.

Enalapril maleate Tablets are 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 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 ENALAPRIL MALEATE TABLETS

#### Do not take Enalapril maleate Tablets

- If you are allergic (hypersensitive) to enalapril maleate, any of the other ingredients in these tablets or other ACE inhibitors (see Section 6 and end of Section 2)
- 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 it was inherited.
- If you are more than 3 months pregnant. (It is also better to avoid Enalapril maleate tablets 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 ever had an allergic reaction to a type of medicine similar to this medicine called an ACE inhibitor
- 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 Enalapril Maleate if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Enalapril maleate Tablets.

#### Warnings and Precautions

You should let your doctor know:

- If you have a heart problem
- If you have a condition involving the blood vessels in the brain
- If you have a blood problem such as low or lack of white blood cells (neutropenia/ agranulocytosis), low blood platelet count (thrombocytopenia) or a decreased number of red blood cells (anaemia)
- 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 kidney problem (including 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 Enalapril maleate Tablets or monitor your blood level of potassium
- If you have been very sick (excessive vomiting) or had bad diarrhoea recently
- If you have diabetes. You should monitor your blood for low blood glucose levels, especially during the first month of treatment. The level of potassium in your blood can also be higher
- If you have a liver problem or develop jaundice (yellowing of the skin and white of the eye)
- If you are having dialysis
- If you are over 70 years of age
- 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 immune system, are taking drugs allopurinol or procainamide, or any combinations of these
- If you think you are (or might become) pregnant. Enalapril maleate Tablets are 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)
- 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
- 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 or for cancer (e.g., temsirolimus, sirolimus, everolimus)
  - Vildagliptin, a medicine used to treat diabetes.

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 tablets".

You should be aware that Enalapril maleate Tablets lowers blood pressure in black patients less effectively than in non-black patients. If you are not sure of any of the above apply to you, talk to your doctor or pharmacist before taking Enalapril maleate Tablets.

#### If you are about to have a procedure:

If you are about to receive any of the following, tell your doctor that you are taking Enalapril maleate Tablets:

- any surgery or receive anesthetics (even at dentist)
- desensitisation treatment with hymenoptera venom (e.g. bee or wasp venom)
- treatment called LDL apheresis to remove cholesterol from your blood machine

If any of the above applies to you, talk to your doctor or dentist before procedure

#### Other medicines and Enalapril maleate Tablets

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines including medicines obtained without a prescription. This includes herbal medicines. Some medicines can affect the way Enalapril maleate Tablets works.

It is especially important to tell your doctor if you are taking any of the following:

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 tablets" and "Warnings and precautions")
- Other medicines that lower blood pressure, such as beta blockers, vasodilators 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 to prevent organ transplant rejection; and heparin, a medicine used to thin blood to prevent clots)
- Lithium, used for the treatment of certain kind of depression
- Tricyclic antidepressants such as amitriptyline used for treating depression
- Medicines for mental problems called 'antipsychotics'
- Certain cough and cold medicines and weight reducing medicines which contain substances called 'sympathomimetic agents'
- Certain pain or arthritis medicines including gold therapy.
- Antidiabetic drugs including oral agents to lower blood sugar and insulin
- Non-steroidal anti-inflammatory drugs (NSAIDs), 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)
- 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".
- A medicine containing a neprilysin inhibitor such as sacubitril (available as fixed-dose combination with valsartan), used in patients with heart failure, and racecadotril. 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 maleate Tablets".

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

#### Enalapril maleate Tablets with food, drink and alcohol

Enalapril maleate tablets can be taken with or without food. Do not drink alcohol while taking Enalapril maleate tablets. It may cause your blood sugar levels to drop too much and you may experience dizziness, light-headedness or faintness.

#### Pregnancy and breast-feeding

##### Pregnancy

You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking Enalapril maleate Tablets 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 Tablets.

Enalapril maleate tablets are 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 Tablets. In the case of an older baby your doctor should advise you on the benefits and risks of taking Enalapril maleate Tablets whilst breast-feeding, compared to other treatments.

##### Driving and using machines

As this medicine may make you feel dizzy or sleepy, you should not drive or operate machinery until you know how the drug affects you.

##### Enalapril maleate tablets contains lactose

This product contains lactose - if you know you have intolerance to some sugars, contact your doctor before use.

### 3. HOW TO TAKE ENALAPRIL MALEATE TABLETS

Always take your medicine exactly as your doctor told you. If you are unsure about how to take your tablets, ask your doctor or pharmacist.

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

You should take your tablet at the same time each day unless your doctor tells you otherwise. If you are taking your medicine twice daily (2 tablets a day), take one tablet in the morning and one in the evening, unless your doctor has told you otherwise.

Recommended dose to be swallowed with a glass of water:

#### Adults

##### High blood pressure:

- The recommended starting dose is from 5mg to 20mg taken once a day
- Some patients may need lower starting dose
- The long term dose is 20mg taken once daily
- The maximal long term dose is 40mg once a day

##### Heart failure:

- The starting dose is 2.5mg taken once a day
- Your doctor will raise this amount step by step until the dose that is right for you has been achieved
- The long term dose is 20mg taken in one or two doses
- The maximal long term dose is 40mg each day, divided in two doses

#### **Elderly (65 years and over)**

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

#### **Patients with kidney problems**

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

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

#### **Use in children and adolescents**

Experience in the use of this medicine 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 recommended starting doses are:

- between 20 kg and 50 kg – 2.5 mg each day
- more than 50 kg – 5 mg each day.

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 who are more than 50 kg.

This medicine is not recommended in newborn babies (first few weeks after birth) and in children with kidney problems.

#### **If you take more Enalapril maleate Tablets than you should**

Do not take more medicine than your doctor tells you to. If you or anyone else has swallowed more tablets than doctor have prescribed, contact your nearest hospital causality department or doctor immediately. 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 Enalapril maleate Tablets**

If you forget to take a dose, 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 Enalapril Tablets**

Do not stop taking your medicine, unless your doctor has told you to.

If you have any further questions on the use of this product ask your doctor or pharmacist.

### **4. POSSIBLE SIDE EFFECTS**

Like all medicines Enalapril maleate Tablets can cause side effects, although not everybody gets them.

If you develop any of the following reactions **stop** taking these tablets and contact your doctor **immediately**:

- Swelling of the face, lips, tongue or throat which may cause difficulty in breathing or swallowing
- Swelling of your hands, feet or ankles
- A sudden, unexpected rash or burning, red or peeling skin
- Ringing in your ears (tinnitus)
- Bone marrow depression (reduction in blood cell count)
- Inflammation of the liver, liver disease, increase in liver enzymes or bilirubin (measured in tests), jaundice (yellowing of the skin and/or eyes)
- Blood disorders including changes in blood values such as lower number of white and red blood cells, lower haemoglobin, lower number of blood platelets
- 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)

You should be aware that black patients are at increased risk of these types of reactions. If any of the above happens, stop taking Enalapril Tablets and talk to doctor straight away.

You may feel dizzy when you start taking Enalapril maleate Tablets. 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 possible side effects include:

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

- Feeling dizzy, weak or sick
- Blurred vision
- Cough

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

- Diarrhoea or abdominal pain, rash
- Headache, fainting (syncope)
- Low blood pressure, changes in heart rhythm, fast heartbeat, angina or chest pain
- Weakness or fatigue, depression
- Increased potassium level, increased levels of creatinine in your blood (both are detected by a test)
- Change in sense of taste, shortness of breath

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

- Indigestion, vomiting, constipation, anorexia (loss of appetite)
- Slow movement of food through your intestine, inflammation of your pancreas
- Irritated stomach (gastric irritations), dry mouth, ulcer, impaired kidney function, kidney failure
- Runny nose or hoarseness
- Fast or uneven heart beats (palpitations)
- Anaemia (including aplastic and haemolytic)
- Confusion, difficulty sleeping, sleepiness, nervousness
- Feeling your skin prickling or being numb
- vertigo (spinning sensation)
- asthma-associated tightness in chest
- Increased perspiration
- Itching or nettle rash
- Loss of hair
- Muscle cramps, flushing, generally feeling unwell (malaise), high temperature (fever), erectile dysfunction (impotence)
- High level of proteins in your urine (measured in a test)
- Low level of blood sugar or sodium, high level of blood urea (all measured in blood tests)

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

- 'Raynaud's phenomenon' where your hands and feet may become very cold and pale due to low blood flow
- 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 in breathing (pneumonia)
- Inflammation of the cheeks, gums, tongue, lips, throat
- Lower amount of urine produced
- Skin disorder due to an allergic reaction or infection called Erythema multiforme
- Enlarged breasts in men
- Swollen glands in neck, armpit or groin
- '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)

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

- Swelling in your intestine (intestinal angioedema)

**Not known** (frequency cannot be estimated from the valuable 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 Yellow Card Scheme:

[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.