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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 it is 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 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

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

Talk to your doctor or pharmacist before taking Enalapril maleate tablets

- 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 (rapid swelling under the skin in area such as the throat) is increased:
 - sirolimus, everolimus and other medicines belonging to the class of mTOR inhibitors (used to avoid rejection of transplanted organs)

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 if"

Take special care with Enalapril maleate Tablets

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 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 are on a salt restriction diet, are taking potassium containing medicines or supplements, potassium-sparing agents, salt substitutes or low-salt milk.
- 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 breast-feeding or about to start breast feeding (see Breast-feeding section)

You should be aware that Enalapril maleate Tablets lowers blood pressure in black people 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 or salt substitutes containing potassium, diuretics (water tablets, in particular those so called potassium sparing), other drugs which can increase potassium in your body (such as heparin and co-trimoxazole also known as trimethoprim/sulfamethoxazole)
- 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
- Barbiturates (sedatives used for sleeplessness or epilepsy)
- Cholestyramine (used to help control cholesterol levels)
- Medicines for the treatment of cancer
- Antidiabetic drugs including oral agents to lower blood sugar and insulin
- Allopurinol (used to treat gout)
- Ciclosporin (immunosuppressive agents for autoimmune disorders)
- Procainamide used to treat abnormal heart rhythms
- 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)
- Corticosteroids (used to treat certain conditions such as rheumatism, arthritis, allergic conditions, asthma or certain blood disorders)
- Antacids (used for the relief of indigestion)
- Alcohol
- Medicines which are most often used to avoid rejection of transplanted organs (sirolimus, everolimus and other medicines belonging to the class of mTOR inhibitors). See section "Warnings and precautions".

If you are 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 and drink

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, 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.

■ Black

Artwork Same Size
Size : 280 x 360 mm

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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 casualty 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:

- If you develop severe dizziness or lightheadedness (especially at the start of the treatment or when the dose is increased)
- 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
- Sore throat or fever
- 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)
- 'Stevens-Johnson syndrome' a serious skin condition where you have reddening or scaling of your skin, blistering or raw sores, or detachment of the top layer of skin from bottom layers
- Blood disorders including changes in blood values such as lower number of white and red blood cells, lower haemoglobin, lower number of blood platelets

You should be aware that black patients are at increased risk of these types of reactions. If any of the above happens, stop taking Innovance 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
- Allergic reactions with swelling of the face, lips, tongue or throat with difficulty in swallowing or breathing
- 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, sore throat or hoarseness
- Sudden fall in blood pressure (you may experience dizziness, fainting or light-headedness)
- 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 heart or brain)
- Anaemia (including aplastic and haemolytic)
- Stroke (possibly due to very low blood pressure in certain high-risk patients)
- 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), 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)
- ringing in your ears (tinnitus)

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
- 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
- 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
- 'Stevens-Johnson syndrome' and 'toxic epidermal necrolysis' (serious skin conditions where you have reddening and scaling of the 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 gall bladder 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)

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 or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE ENALAPRIL MALEATE TABLETS

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

Do not take Enalapril maleate tablets after the expiry date on the carton; the expiry date refers to the last day of the month.

Do not store above 25°C.

Store in the original packaging.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Enalapril maleate Tablets contain

The **active** substance is Enalapril maleate 2.5mg, 5mg, 10mg or 20mg per tablet.

The **other** ingredients are Lactose monohydrate, Maize starch and Glycerol palmitostearate.

What Enalapril maleate Tablets looks like and contents of the pack

Enalapril maleate Tablets are white to off-white round flat beveled edged tablets marked with '2.5' (2.5mg), '5' (5mg), '10' (10mg) or '20' (20mg), on one side and break line on the other.

They are supplied in blister packs of 28 tablets and bottles containing 50 tablets

Not all pack sizes may be marketed.

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