Uncommon side effects (affecting between 1 in 100 and 1 in 1000 people)
- Iron deficiency (anaemia) including splenic and haemolytic
- Sudden fall in blood pressure
- Fast or uneven heart beats (palpitations)
- Herto-geriatric symptoms
- Confusion, sleeplessness or nervousness
- Tingling or burning sensation of the skin (parasthesias)
- Rupture neck dive
- Asthma-associated tightness in chest
- Slow movement of food through your stomach, intestines or bladders
- Asthma or bronchitis
- Reduced lung function
- Impaired kidney function
- Kidney failure
- 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 side effects.

Very common side effects
- Feeling dizzy, weak or sick
- Blurred vision

Other possible side effects
- Photosensitivity
- Peeling of the skin (exfoliative dermatitis, erythroderma)
- Liver or gallbladder problems such as lower liver function, inflammation
- Impaired kidney function
- Kidney failure
- Autoimmune disease
- Bone marrow depression
- Strange dreams or sleep problems

Rare side effects (affecting between 1 in 1000 and 1 in 10000 people)
- Low level of blood sugar or sodium, high level of blood urea (all measured in a blood test)
- High-level of proteins in your urine (measured in a test)

Side effects (affecting between 1 in 1000 and 1 in 1000 people)
- Strange dreams or sleep problems
- Swollen glands in neck, armpit or groin
- Autoimmune disease
- Raynaud’s phenomenon, where your hands and feet may become very cold and white due to low blood flow
- Accumulation of fluid or other substances in the lungs (as seen on X-rays)
- Pulmonary infiltrates
- Inflammation of the nose and lung causes difficulty breathing (pneumonia)
- Inflammation of the cheeks, gums, tongue, lips, throat
- Blistering of skin (pemphigus)
- Low albumin (albumin being a type of sugar)
- Enlarged breasts in men (gynecomastia)

Very rare (affecting less than one person in 10,000)
- Swelling of the intestine

Not known:
- Excessive release of antidiuretic hormone from the pituitary gland or other source, 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 (arthritis/rheumatoid), rash or other skin manifestations may occur.

If any of these side effects gets serious, or if you notice any side effects not listed in this leaflet, please talk to your doctor or pharmacist.

Reporting of side effects: If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Enalapril Tablets
- Do not store above 25 °C. Store in the original package. Do not put them into another container as they might get mixed up. Keep them in the package you got them in.
- Keep out of reach of children.
- Do not use Enalapril Tablets after the expiry date which is stated on the blister and the carton after EXPIR or EXP DATE.
- 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 Tablets contain The active substance is Enalapril Maleate. The other ingredients are lactose, magnesium stearate and hypromellose.

What Enalapril Tablets look like and contents of the pack
Enalapril tablets are white circular biplanar uncoated with 5, 10 or 20 embossed on one face and a score line on the other. They are supplied in blister packs of 28 tablets.

To listen or request this copy of the leaflet in Braille, large print or audio please call 0300 831 1590 (UK only).

Please be ready to give the following information:

Product name Reference number
- Enalapril Maleate 5mg tablets PL 21880/0003
- Enalapril Maleate 10mg tablets PL 21880/0004
- Enalapril Maleate 20mg tablets PL 21880/0005

This leaflet was last revised in May 2017

Enalapril tablets are white circular biplanar uncoated with 5, 10 or 20 embossed on one face and a score line on the other. They are supplied in blister packs of 28 tablets.

Enalapril Maleate 5, 10 and 20 mg Tablets (referred to as Enalapril Tablets in this leaflet) are and what they are used for

1. What Enalapril Tablets are and what they are used for
Enalapril tablets contain the active ingredient enalapril maleate. This belongs to a group of medicines called Angiotensin converting enzyme inhibitors (ACE inhibitors). It works by causing blood vessels to relax, lowering blood pressure and helping maintain the supply of blood and oxygen to the heart.

Enalapril Tablets are used:
- to treat high blood pressure (hypertension),
- to treat heart failure (weakening of heart function). It can lower blood pressure and help prevent the symptoms of heart failure such as walking, or swelling of the ankles and feet.

2. What you need to know before you take Enalapril Tablets
Do not take Enalapril Tablets if you are allergic (hypersensitive) to enalapril maleate or any of the other ingredients of Enalapril Tablets (see Section 6 and end of Section 2).
- if you have ever had an allergic reaction to a type of medicine similar to Enalapril tablets called an ACE inhibitor (see Section 4).
- if you have ever had swelling of your face, lips, mouth, tongue or throat which caused difficulty in swallowing or breathing when the reason was unknown or it was inherited.

Marketing Authorisation Holder and Manufacturer:
MEDREICH P/L
Warwick House, Place Tow Comunt, Fulham, SW6 7HF, UK.
E-mail: info@medreich.co.uk

§ 20180601-V11210000-V2

PACKGAE LEAFLET: INFORMATION FOR THE USER

Enalapril Maleate 5/10/20 mg Tablets
Enalapril Maleate
Read all of this leaflet carefully before you start taking this medicine. 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 of doubt, this includes any possible effects not listed in this leaflet. See section 4.

What is in this leaflet
1. What Enalapril Maleate 5, 10 and 20 mg Tablets (referred to as Enalapril Tablets in this leaflet) are and what they are used for
2. What you need to know before you take Enalapril Tablets
3. How to take Enalapril Tablets
4. Possible side effects
5. How to store Enalapril Tablets
6. Contents of the pack and other information

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§ 20180601-V1

Space for Pharma Code
• If you have diabetes or impaired kidney function and you are treated with an mTOR inhibitor (e.g., temsirolimus, sirolimus, everolimus; medicines called immunosuppressants, used to treat certain types of cancer or to prevent the body's immune system from rejecting a transplanted organ).
• If you are on a potassium-sparing diuretic. (This may include medicines such as spironolactone, eplerenone, amiloride, triamterene, or other potassium-sparing diuretics. If you are taking any of these medicines, you should talk to your doctor or pharmacist before taking Enalapril.)
• Talk to your doctor or pharmacist before taking Enalapril Tablets if any of the above applies to you. If you are not sure talk to your doctor or pharmacist before taking Enalapril Tablets.
• Do not take Enalapril Tablets if you are breastfeeding (see section 4.6). If you have been very sick (excessive vomiting) or had bad diarrhoea, your body may have produced a lot of potassium in your blood which can be serious. You should check your potassium level and tell your doctor if you have high potassium levels in your blood.
• You should not drive or operate machinery until you know how the drug affects you.
• High Blood Pressure

Always take your medicine exactly as directed by your doctor. If you are not sure talk to your doctor or pharmacist before taking Enalapril Tablets. If you forget to take Enalapril Tablets
• Take the next dose as usual.
• If you take more Enalapril Tablets than you should, talk to your doctor or pharmacist. Enalapril Tablets are not recommended in new born babies and in children with kidney problems. If you take more Enalapril Tablets than you should
• You should not drive or operate machinery until you know how the drug affects you.
• Enalapril Tablets contain lactose: this product contains lactose - if you know you have intolerance to some sugars, contact your doctor before use.
• If you are taking any of the above medicines, you should talk to your doctor or pharmacist before taking Enalapril Tablets.
• If you are having dialysis – 2.5mg daily. On days which you are not having dialysis, your doctor will advise you on the benefits and risks of taking Enalapril Tablets while blood-pressure-lowering compared to other treatments.
• If you are undergoing treatment for cancer, ask your doctor or pharmacist. Patients with kidney failure

Heart Failure

• The usual starting dose is 1.25mg taken once daily.
• The usual long term dose is 20mg taken daily in one or two doses.
• The maximum dose is 40mg daily, divided in two doses.

Children

• If you are receiving treatment for cancer, ask your doctor or pharmacist.
• Patients with kidney failure

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Diseases of the blood and blood-forming organs and immunity disorders

• Enalapril Tablets are not recommended in young babies and in children with kidney problems. If you take more Enalapril Tablets than you should

• You should not drive or operate machinery until you know how the drug affects you.

• If you have ever had an allergic reaction, you should not take this medicine.
• You should check your blood pressure at regular intervals.
• If you have a blood problem such as lower or lack of white blood cells (thrombocytopenia), decreased number of red blood cells (anaemia). Not recommended in young babies and in children with kidney problems. If you take more Enalapril Tablets than you should

• If you have diabetes or impaired kidney function and you are treated with an mTOR inhibitor (e.g., temsirolimus, sirolimus, everolimus; medicines called immunosuppressants, used to treat certain types of cancer or to prevent the body's immune system from rejecting a transplanted organ).
• If you are on a potassium-sparing diuretic. (This may include medicines such as spironolactone, eplerenone, amiloride, triamterene, or other potassium-sparing diuretics. If you are taking any of these medicines, you should talk to your doctor or pharmacist before taking Enalapril.)
• If you are on a salt restriction diet.
• If you have ever had an allergic reaction. The signs may have been itching, wheezing or swelling of the face, lips, hands, mouth and throat with difficulty swallowing and breathing. You should check your blood pressure at regular intervals.
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• Patients with kidney failure

• If you are taking an mTOR inhibitor (e.g., temsirolimus, sirolimus, everolimus; medicines used to treat certain types of cancer or to prevent the body's immune system from rejecting a transplanted organ).
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• If you are taking any of the following medicines used to treat high blood pressure:
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• If you are receiving a treatment called LDL apheresis to remove cholesterol from your blood by machine.
• If you have blood pressure which you think is too low or too high, or any combinations of these followed by:
• If you are being treated for high blood pressure:

• Medicines which contain potassium e.g. spironolactone, eplerenone, triamterene, amiloride. Your dose will be decided by the doctor and will depend on how well your kidneys are working.
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