

PACKAGE LEAFLET: INFORMATION FOR THE USER
ENALAPRIL 5, 10 and 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. What Enalapril Tablets are and what they are used for
2. Before you take Enalapril Tablets
3. How to take Enalapril Tablets
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1. WHAT ENALAPRIL TABLETS ARE AND WHAT THEY ARE USED FOR

These tablets contain enalapril maleate. Enalapril belongs to a group of medicines known as 'ACE inhibitors', which work by widening your blood vessels.

They are used to treat:

- High blood pressure
- Heart failure (symptoms of which include tiredness after light exercise, breathlessness and swelling of your ankles and legs).

They are also used to prevent heart failure and heart attacks in people who have heart problems but have no symptoms.

2. BEFORE YOU TAKE ENALAPRIL TABLETS

Do not take Enalapril Tablets:

- if you are allergic (hypersensitive) to Enalapril or any of the other ingredients of Enalapril Tablets. The symptoms of an allergic reaction include itching, nettle rash, wheezing or swelling of the hands, throat, mouth or eyelids. You can find a list of the ingredients of this medicine in Section 6 of this leaflet
- if you are more than 3 months pregnant. (It is also better to avoid Enalapril in early pregnancy - see pregnancy section)
- if you have a heart condition called 'aortic stenosis' or 'outflow obstruction' (narrowing of a valve in your major artery (aorta) causing restricted blood flow around your body).

If you think any of the above points apply to you, do not take the tablets. Talk to your doctor first and follow the advice given.

Take special care with Enalapril Tablets

Tell your doctor before taking these tablets if any of the following points apply to you:

- if you have kidney disease or are a dialysis patient
- if you suffer from excessive vomiting or diarrhoea
- if you are on a low salt diet (sometimes called a low sodium diet)
- if you think you are (or might become) pregnant. Enalapril 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 this stage (see pregnancy section)
- if you are Afro-Caribbean as Enalapril may not work as well as expected

If you are due to undergo any of the following procedures you must tell the doctor who is treating you that you are taking Enalapril tablets:

- treatment called LDL apheresis to remove cholesterol from your blood by a machine
- any surgery or anaesthetics (even at the dentist)
- desensitisation treatment to reduce the effects of an allergy to bee or wasp stings

Tests before and while taking this medicine

Your doctor will monitor your blood pressure before and during your treatment with this medicine. You may also be required to have a blood test to check that your kidneys are working properly before you start taking the tablets and at intervals during your treatment.

Taking other medicines

Tell your doctor before taking this medicine if you are already taking any of the following:

- Other medicines to lower your blood pressure such as beta blockers (e.g. Propranolol), methyldopa, calcium antagonists and diuretics (water tablets)
- Potassium supplements or salt substitutes containing potassium
- Allopurinol (used to treat gout)
- Procainamide (used to treat abnormal heart rhythms)
- Non steroidal anti-inflammatory drugs (NSAIDs) e.g. diclofenac, ibuprofen
- Antacids used to treat heartburn or digestive discomfort
- Immunosuppressive drugs e.g. cyclosporine or corticosteroids
- Medicines used to treat diabetes e.g. insulin
- Medicines to treat pain or to help you sleep e.g. morphine
- Medicines to treat some psychiatric illnesses e.g. antipsychotics and lithium
- Medicines to treat cancer
- Medicines such as ephedrine, noradrenaline and adrenaline

Tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Taking Enalapril Tablets with food and drink

The absorption of Enalapril Tablets is not affected by food intake.

Alcohol and Enalapril Tablets can have additive effects and may cause dizziness or light-headedness. Your doctor will have told you that you should always keep your alcohol intake to a minimum. If you are concerned about how much alcohol you can drink while you are taking Enalapril Tablets, discuss this with your doctor.

If you are on a low salt diet (sometimes called a low sodium diet) tell your doctor before taking these tablets.

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 before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Enalapril. Enalapril 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. Breastfeeding newborn babies (first few weeks after birth), and especially premature babies, is not recommended whilst taking Enalapril.

In case of an older baby your doctor should advise you on the benefits and risks of taking Enalapril whilst breast-feeding, compared with other elements.

Driving and using machines

Enalapril Tablets can cause side effects such as dizziness, light headedness, headache, tiredness, confusion and blurred vision. Do not drive or operate machines if you experience any of these side effects.

Important information about some of the ingredients of Enalapril Tablets

These tablets contain Lactose which is a type of sugar. Contact your doctor before taking these tablets if you are Lactose intolerant.

3. HOW TO TAKE ENALAPRIL TABLETS

Always take Enalapril Tablets exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. The dose you take will depend on your condition and whether you are taking any other treatment.

Usual dose for high blood pressure:

The normal starting dose is 5 mg once a day. This is gradually increased up to 10-20 mg once daily. The maximum dose is 40 mg a day.

Some patients, including the elderly (over 65 years of age) may start on a lower dose of 2.5 mg once a day.

Usual dose for heart failure:

The normal starting dose is 2.5 mg a day. This is gradually increased up to 20 mg a day, given either once daily or in 2 doses of 10 mg according to your doctor's advice.

If Taking Enalapril tablets with a diuretic (water tablet):

The recommended initial dose is 2.5 mg a day. If possible, your doctor will ask you to stop taking your diuretic tablets 2-3 days before starting to take Enalapril Tablets.

Take your tablet at the same time each day unless your doctor tells you otherwise. If you are taking 2 tablets a day, take one in the morning and one in the evening, unless your doctor has told you otherwise.

If you take more Enalapril Tablets than you should:

If you take too many tablets by mistake contact your doctor IMMEDIATELY.

If you forget to take Enalapril Tablets:

Do not take a double dose to make up for a forgotten tablet. If you miss a dose just carry on with the next one as normal, but make sure you tell your doctor.

If you stop taking Enalapril Tablets:

Your doctor will tell you when you should stop taking Enalapril Tablets. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, these tablets can cause side effects, although not everybody gets them.

Serious side effects - If you get any of the side effects shown in the list below STOP TAKING the tablets and seek medical attention IMMEDIATELY:

- severe dizziness or light-headedness
- itching
- blistering of the skin, mouth, eyes or genitals
- swelling of the hands, feet, mouth, throat or face (Afro Caribbean patients may have a higher risk of this side effect)
- shortness of breath or wheezing
- pain or tightness in the chest, neck, shoulders or arms
- numbness or weakness on one side of the body (e.g. a drooping arm, leg or lower eyelid, or a dribbling mouth)
- slurred speech and/or blurred vision
- confusion or unsteadiness

These could be the sign of kidney failure, heart attack, stroke or a serious allergic reaction (such as Stevens-Johnson syndrome or toxic epidermal necrolysis).

Other serious side effects - If you get any of the side effects shown in the list below STOP TAKING the tablets and seek medical attention IMMEDIATELY:

- Pancreatitis - symptoms include abdominal pain, nausea
- liver problems including hepatitis and jaundice (yellowing of the skin or eyes)
- build up of fluid in the lungs causing difficulty breathing
- light-headedness when you stand up (especially at the start of treatment or when the dose is increased)

Other side effects - If you experience any of the side-effects listed below and you are worried, tell your doctor:

- Asthma or Cough
- Chest pain
- Palpitations or Irregular heartbeat
- Indigestion
- Constipation
- Diarrhoea
- Digestive problems
- Loss of appetite
- Urinating less
- Sore mouth and tongue
- Dizziness or Headaches
- Tiredness or Weakness
- Fainting
- Feeling sick or being sick
- Muscle cramps
- Feeling generally unwell
- Depression or Confusion
- Difficulty in sleeping
- Nervousness
- Pins and needles
- Vertigo
- Sore throat and hoarseness
- Sexual inability in men
- Fever or Flushing
- Increased sensitivity to sunlight
- Runny nose
- Ringing in the ears
- Blurred vision
- Taste alteration
- Hair loss
- Excessive sweating
- Swollen or painful muscles or joints

Whilst you are taking this medicine it may affect tests your doctor may perform on blood or urine samples. Please remind your doctor that you are taking Enalapril tablets if ever he/she wants to carry out such a test.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, tell your doctor or pharmacist.

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 pack in which they are supplied.

Keep out of the reach and sight of children.

Do not use Enalapril Tablets after the expiry date which is stated on the blister and the carton after EXP 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. FURTHER INFORMATION

What Enalapril Tablets contains

The active substance is Enalapril Maleate. The other ingredients are Lactose; Maize Starch and Glycerol Distearate

What Enalapril Tablets look like and contents of the pack

Each tablet is white, circular, biplaner and uncoated with either 5, 10 or 20 embossed on one face and a score line on the other.

Enalapril 5mg, 10mg and 20mg tablets are available in packs of 28.

Marketing Authorisation Holder and Manufacturer

The Product Licence holder for your tablets is PharmaDreams Ltd, Old Police Station, Church Street, Swadlincote, DE11 8LN

Your tablets are made and distributed by PharmaDreams Ltd, Old Police Station, Church Street, Swadlincote, DE11 8LN

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If you would like this leaflet in a different format please contact the licence holder at the following address: Atrium Court, The Ring, Bracknell, Berkshire, RG12 1BW.

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