

PHARMANIAGA ENALAPRIL TABLET

Enalapril maleate (5mg/ 20mg)

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What Pharmaniaga Enalapril Tablet is used for

Pharmaniaga Enalapril Tablet is used to treat:

- High blood pressure – also called hypertension.
- Heart failure – where the heart has difficulty pumping blood around your body
- 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.

How Pharmaniaga Enalapril Tablet works

Pharmaniaga Enalapril Tablet works by widening your blood vessels. This lowers your blood pressure. It also makes it easier for your heart to pump blood around your body.

Before you use Pharmaniaga Enalapril Tablet

-When you must not use it

- You have ever had an allergic reaction with swelling of the face, lips, tongue or throat with difficulty in swallowing or

- breathing.
- You think you are (or might become) pregnant, Pharmaniaga Enalapril Tablet 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 that stage.

- Before you start to use it

Check with your doctor or pharmacist before taking your medicine if:

- You have a heart problem.
- You have a condition involving the blood vessels in the brain.
- 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).
- You have a liver problem.
- 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 or monitor your blood level of potassium.
- You are having dialysis.
- You have been very sick (excessive vomiting) or had bad diarrhoea recently.
- You are on a salt-restricted diet, are taking potassium supplements, potassium-sparing agents, or potassium-containing salt substitutes.
- You are over 70 years of age.
- 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.
- You have low blood pressure

(you may notice this as faintness or dizziness, especially when standing).

- You are breast-feeding or about to start breast-feeding.

- Taking other medicines

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. This is because Enalapril can affect the way some medicines work. Also, some other medicines can affect the way Enalapril works:

In particular tell your doctor or pharmacist if you are taking any of the following medicines:

- Other medicines to lower blood pressure, such as beta-blockers or water tablets (diuretics).
- Medicines containing potassium (including dietary salt substitutes).
- Medicines for diabetes (including oral antidiabetic medicines and insulin).
- Lithium (a medicine used to treat a certain kind of depression).
- Medicines for depression such as Amitriptyline.
- Medicines for mental problems such as chlorpromazine.
- Non-steroidal anti-inflammatory drugs, such as Indomethacin or diclofenac (for pain or inflammation).
- Alcohol.

If you are not sure if any of the above applied to you, talk to your doctor or pharmacist.

How to use Pharmaniaga Enalapril Tablet

- How much to use

Always take Pharmaniaga Enalapril Tablet exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

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

High Blood Pressure

- The usual starting dose ranges from 10 to 20 mg taken once a day.
- Some patients may need a lower starting dose.
- The usual long term dose is 20 mg taken once a day.
- The maximal long term dose is 40 mg taken once a day.

Heart Failure

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

Patients with kidney problems

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

- Mild kidney problem – 5 mg to 10 mg each day
- Moderate kidney problems – 2.5 mg to 5 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.

- When to use it

Your doctor will tell you when to take it. Read the label on the carton to follow exactly what your doctor has told you. Try to take your tablet at the same time each day.

- How long to use it

The prescription is almost always life-long. Your doctor would monitor your condition on regular basis and advice if a change is required. Do not stop taking Pharmaniaga Enalapril Tablet without talking to your doctor.

- If you forget to use it

If you forget to take a tablet, 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 use too much (overdose)

If you take more Pharmaniaga Enalapril Tablet 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-headed or dizziness. This is due to a sudden or excessive drop in blood pressure.

While you are using it

You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking Pharmaniaga Enalapril Tablet before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Enalapril.

Pharmaniaga Enalapril Tablet 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.

If you are about to have any of the following, tell your doctor that you are taking Pharmaniaga Enalapril Tablet:

- 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 applied to you,

talk to your doctor or dentist before the procedure.

-Things you must not do

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

If you have any further questions on the use of this product, 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.

Unless you develop an allergic reaction, you must not stop or change the schedule of taking Pharmaniaga Enalapril Tablet without consulting your doctor. You may feel dizzy or sleepy while taking Pharmaniaga Enalapril Tablet. If this happens, do not drive or use any tools or machines.

-Things to be careful of

Tell your doctor if you are breastfeeding or about to start breastfeeding.

Breast-feeding newborn babies (first few weeks after birth), and especially premature babies, is not recommended whilst taking Pharmaniaga Enalapril Tablet. In the case of an older baby your doctor should advise you on the benefits and risks of taking Pharmaniaga Enalapril Tablet whilst breast-feeding, compared to other treatments. If you are not sure if any of the above applied to you, talk to your doctor or pharmacist before taking Enalapril.

Side effects

Like all medicines Pharmaniaga Enalapril Tablet can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

Stop taking Enalapril and talk to a doctor straight away, if you notice any of the following:

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

If any of the above happens, stop

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taking Pharmaniaga Enalapril Tablet and talk to a doctor straight away.

When you start taking Pharmaniaga Enalapril Tablet 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

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

Common

- Low blood pressure, changes in heart rhythm, fast heartbeat, angina or chest pain.
- Headache, fainting (syncope).
- Change in sense of taste, shortness of breath.
- Diarrhoea or abdominal pain, rash.
- Tiredness (fatigue), depression.
- Allergic reactions with swelling of the face, lips, tongue or throat with difficulty in swallowing or breathing.
- Increased blood potassium level, increased levels of creatinine in your blood (both are usually detected by a test).

Uncommon

- 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).
- Anaemia (including aplastic and haemolytic).
- Stroke (possibly due to very low blood pressure in high-risk patients).
- Confusion, sleeplessness or sleepiness, nervousness.

- Feeling your skin prickling or being numb.
- Vertigo.
- Ringing in your ears (tinnitus).
- Runny nose, sore throat or hoarseness.
- Asthma.
- Slow movement of food through your intestine, inflammation of your pancreas.
- Being sick (vomiting), indigestion, constipation, anorexia.
- Irritated stomach (gastric irritations), dry mouth, ulcer, impaired kidney function, kidney failure.
- 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 a blood test).

Rare

- ‘Raynaud’s phenomenon’ where your hands and feet may become very cold and white due to low blood flow.
- 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.
- Autoimmune diseases.
- Strange dreams or sleep problems.
- Pulmonary infiltrates.
- Inflammation of your nose.
- Pneumonia.
- Inflammation of the cheeks, gums, tongue, lips, throat.
- Lower amount of urine produced.
- Erythema multiforme.
- ‘Stevens-Johnson syndrome’ a

serious skin condition where you have reddening and scaling of your skin, blistering or raw sores, or detachment of the top layer of skin from bottom layers.

- Liver problems such as lower liver function, inflammation of your liver, jaundice (yellowing of the skin or eyes), higher levels of liver enzymes or bilirubin (measured in a blood test).
- Enlargement of the mammary glands in males.

Very Rare

- Swelling in your intestine (intestinal angioedema).

If any of these side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist. You can ask your doctor or pharmacist for more information about side effects. Both have a more complete list of side effects

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public → Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety).

Storage and Disposal of Pharmaniaga Enalapril Tablet - Storage

Keep out of the reach and sight of children. Do not use Pharmaniaga Enalapril Tablet after the expiry date which is stated on the carton and the blister strip. The expiry date refers to the last day of that month. Do not store above 30°C. Store your tablets in the original package. Keep the blister strip in the carton. This will protect your medicine from light and moisture.

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- Disposal

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.

Product Description

- What it looks like

Pharmaniaga Enalapril Tablet 5

mg:

White, barrel shaped tablets, Pharmaniaga icon on one side and scored on the other.

Pharmaniaga Enalapril Tablet 20 mg:

Peach, barrel shaped tablets, plain on one side and scored on the other.

Pharmaniaga Enalapril Tablet 5mg

- Ingredients:

Active ingredient(s):-

Pharmaniaga Enalapril Tablet 5 mg contains Enalapril maleate 5mg

Inactive ingredient(s):-

Lactose Monohydrate, Corn Starch, Starch 1500, Maleic Acid, Povidone 30, Magnesium Stearate and Purified Water.

Pharmaniaga Enalapril Tablet 20mg

- Ingredients:

-Active ingredient(s):-

Pharmaniaga Enalapril Tablet 20 mg contains Enalapril maleate 20mg

-Inactive ingredient(s):-

Lake Sunset Yellow, Cornstarch, Lactose Monohydrate, Magnesium Stearate, Maleic Acid, Povidone (Kollidon 30) and Starch.

- MAL number(s):

Pharmaniaga Enalapril Tablet 5

mg:

MAL20034480AZ

Pharmaniaga Enalapril Tablet 20

mg:

MAL20034478AZ

Manufacturer:

Pharmaniaga Manufacturing Berhad (60016-D),
11A, Jalan P/1, Kawasan Perusahaan Bangi, 43650 Bandar Baru Bangi, Selangor Darul Ehsan, Malaysia.

Product Registration Holder:

Pharmaniaga Manufacturing Berhad (60016-D),
11A, Jalan P/1, Kawasan Perusahaan Bangi, 43650 Bandar Baru Bangi, Selangor Darul Ehsan, Malaysia.

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