

Applicant: Unimed Healthcare (Pty) Ltd

Product Name: Enalapril 2,5/5/10/20 mg Unimed

Dosage form and strength: Tablets containing 2,5 mg, 5 mg, 10 mg and 20 mg enalapril maleate per tablet.

SCHEDULING STATUS

S3

ENALAPRIL 2,5 mg UNIMED, 2,5 mg tablets (Enalapril Maleate)

ENALAPRIL 5 mg UNIMED, 5 mg tablets (Enalapril Maleate)

ENALAPRIL 10 mg UNIMED, 10 mg tablets (Enalapril Maleate)

ENALAPRIL 20 mg UNIMED, 20 mg tablets (Enalapril Maleate)

Contains lactose monohydrate

Each **ENALAPRIL 2,5 mg UNIMED** tablet contains 73,17 mg lactose monohydrate.

Each **ENALAPRIL 5 mg UNIMED** tablet contains 146,3 mg lactose monohydrate.

Each **ENALAPRIL 10 mg UNIMED** tablet contains 139,7 mg lactose monohydrate.

Each **ENALAPRIL 20 mg UNIMED** tablet contains 128,9 mg lactose monohydrate.

Contains sodium

Each **ENALAPRIL 2,5 mg UNIMED** tablet contains 0,5 mg of sodium per tablet.

Each **ENALAPRIL 5 mg UNIMED** tablet contains 1,1 mg of sodium per tablet.

Each **ENALAPRIL 10 mg UNIMED** tablet contains 2,2 mg of sodium per tablet.

Each **ENALAPRIL 20 mg UNIMED** tablet contains 4,3 mg of sodium per tablet.

Read all of this leaflet carefully before you start taking ENALAPRIL UNIMED

Keep this leaflet. You may need to read it again.

If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.

ENALAPRIL UNIMED has been prescribed for you personally and you should not share your medicine with other people. It may harm them,

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even if their symptoms are the same as yours.

What is in this leaflet:

1. What ENALAPRIL UNIMED is and what it is used for
2. What you need to know before you take ENALAPRIL UNIMED
3. How to take ENALAPRIL UNIMED
4. Possible side effects
5. How to store ENALAPRIL UNIMED
6. Contents of the pack and other information

1. What ENALAPRIL UNIMED is and what it is used for

ENALAPRIL UNIMED contains the active substance, enalapril maleate, which belongs to the group of medicines called ACE inhibitors (angiotensin converting enzyme inhibitors).

Enalapril decreases the blood vessel resistance by relaxing the muscles in the blood vessels and that reduces the blood pressure. This also helps improve heart function.

ENALAPRIL UNIMED tablets are used:

- to treat high blood pressure
- to treat heart failure (weakening of heart function)
- to prevent the signs of heart failure (the signs include shortness of breath and swelling of the ankles and feet).

2. What you need to know before you take ENALAPRIL UNIMED

Do not take ENALAPRIL UNIMED

- If you are allergic (hypersensitive) to enalapril or any of the other ingredients in the formulation of ENALAPRIL UNIMED (listed in section 6).
- If you are pregnant or breastfeeding
- If you have porphyria

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- If you take other blood pressure medicines such as those that increase urine formation (water pills)
- If you have a kidney disease
- If you have a history of intolerance of similar medicines
- Any member of your family has had an allergic reaction to these medicines or you have ever had swelling of your face, eyelids, lips, mouth, tongue or throat which caused difficulty in swallowing or breathing (angioedema) when the reason why was not known or it was inherited
- You have diabetes or impaired kidney function and are treated with a blood pressure lowering medicine containing aliskiren
- If you are taking lithium
- If you have a narrowing of your arteries that carry blood to one or both of your kidneys
- If you have an obstruction of blood flow across the aortic valve in the heart
- if you have moderate to severe renal disorder and you are taking blood pressure medicines called ACE inhibitors like enalapril

Warnings and precautions

Take special care with ENALAPRIL UNIMED

- Tell your doctor immediately if you are planning to get pregnant or expect that you are pregnant
- If you should become pregnant while taking ENALAPRIL UNIMED tablets. Stop taking the tablets immediately and contact your doctor
- If you have low blood pressure (you may notice this as faintness or dizziness, especially when standing)
- If you have a condition involving the blood vessels in the brain
- If you have a heart problem

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- If you have kidney disease, including narrowed blood vessels in your kidneys (renal artery stenosis) or recently had a kidney transplant. 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 UNIMED or monitor your blood level for potassium
- If you have a liver problem
- 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, 'angioneurotic oedema' or 'angioedema'. The signs include itching, red marks on the hands, feet and throat, swelling of the face, around the eyes, lips, tongue or throat with difficulty in swallowing or breathing. You should be aware that black patients are at increased risk of these type of reactions to ACE inhibitors
- If you are a dialysis patient, are taking diuretics (water tablets), are on a salt restriction diet, or have suffered from excessive vomiting or 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 take extra potassium in your diet or a salt substitute that contains potassium
- If you have collagen vascular disease (e.g., lupus erthematosus, rheumatoid arthritis or scleroderma), are on therapy that suppresses your immune system, are taking the drugs allopurinol or procainamide, or any combinations of these
- 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, etc.), in particular if you have diabetes-related kidney problems
 - aliskiren ,

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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 UNIMED** "

- You should be aware that 'ENALAPRIL UNIMED' lowers the blood pressure in black patients less effectively than in non-black patients
- If you have developed a cough
- If you are undergoing surgery
- If you are about to have any of the following, tell your doctor that you are taking 'ENALAPRIL UNIMED'
 - Any surgery or receive anaesthetics (even at the dentist)
 - A treatment to remove cholesterol from your blood called 'LDL apheresis'
- if you are taking blood pressure medicines called ACE inhibitors like enalapril since taking them together with ENALAPRIL UNIMED may decrease kidney function.

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

Children and adolescents

Safety and efficacy in children have not been established.

Other medicines and ENALAPRIL UNIMED

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

Tell your doctor or pharmacist if you are taking any of the following medicines:

- Medicines containing potassium (including dietary salt substitutes), other drugs which can increase potassium in your body (such as heparin and co-trimoxazole also known as trimethoprim/sulfamethoxazole)
- Water tablets (potassium sparing diuretics) such as spironolactone, eplerenone, triamterene or amiloride

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- Other medicines to lower blood pressure, such as betablockers, angiotensin- receptor-blockers, water tablets (diuretics) such as thiazides, furosemide, bumetanide, a medicine called aliskiren or medicines for chest pain (angina) such as nitroglycerine
- If you are taking an angiotensin II receptor blocker (ARB) or aliskiren (see also information under the headings "Do not take ENALAPRIL UNIMED if" and "Take Special care with ENALAPRIL UNIMED"
- Lithium (for some types of mental illness)
- Medicines used for stiffness and inflammation associated with painful conditions, particularly those affecting your muscles, bones and joints:
- non-steroidal anti-inflammatory drugs, 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 used to treat abnormal blood glucose levels (antidiabetics)
- Injectable gold (sodium aurothiomalate)- medicines used to block inflammation in the body.

ENALAPRIL UNIMED with food and drink

ENALAPRIL UNIMED can be taken with or without food.

Pregnancy and breastfeeding

Do not take ENALAPRIL UNIMED if you are pregnant, are considering becoming pregnant or breastfeeding.

ENALAPRIL UNIMED may harm your unborn baby. It is known that ENALAPRIL UNIMED is not safe for pregnant women or mothers that breast-feed their babies. Do not breastfeed while taking ENALAPRIL UNIMED tablets.

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If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking ENALAPRIL UNIMED.

Driving and using machines

ENALAPRIL UNIMED tablets can cause dizziness and headaches. Do not drive or operate any machinery until you know how ENALAPRIL UNIMED will affect your ability to drive or concentrate.

ENALAPRIL UNIMED contains Lactose

Lactose is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

ENALAPRIL UNIMED contains Sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take ENALAPRIL UNIMED

Do not share medicines prescribed for you with any other person.

Always take ENALAPRIL UNIMED tablets exactly as your doctor has instructed you.

You should check with your doctor or pharmacist if you are unsure.

Duration of administration

Your doctor will tell you how long your treatment with ENALAPRIL UNIMED will last.

Do not stop treatment early. If you have the impression that the effect of ENALAPRIL UNIMED is too strong or too weak, tell your doctor or pharmacist.

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Method of administration

The dose of ENALAPRIL UNIMED tablets might be different for different patients. The number of doses you take each day, the time allowed between doses, and the length of time you take this medicine depend on the medical problem for which you are taking ENALAPRIL UNIMED. ENALAPRIL UNIMED, unless otherwise prescribed, should be used as follows: ENALAPRIL UNIMED is to be taken once daily at the same time of the day with a half a glass of liquid .

If you take more ENALAPRIL UNIMED than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

Take this leaflet and the rest of the remaining tablets with you so the doctor will know what you have taken.

If you forget to take ENALAPRIL UNIMED:

Try to take ENALAPRIL UNIMED as prescribed. However, if you forget to take a dose, take the missed dose as soon as possible. However, if it is almost time for your next dose, continue to take the next tablets at the usual time. Do not take a double dose.

If you stop taking ENALAPRIL UNIMED:

If you interrupt or end treatment early with ENALAPRIL UNIMED, your condition may return.

4. Possible side effects

ENALAPRIL UNIMED can have side effects.

Not all side effects reported for ENALAPRIL UNIMED are included in this leaflet. Should your general health worsen while taking ENALAPRIL UNIMED, please consult your doctor, pharmacist or other healthcare professional for advice.

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If any of the following happens, stop taking ENALAPRIL UNIMED and tell your doctor immediately or go to the casualty department at your nearest hospital:

- If you begin to itch, develop a raised red skin rash (hives), get short of breath or wheezy and develop swelling of the hands, feet or ankles, face, mouth, lips, tongue or throat, which may cause difficulty in breathing or swallowing
- Fainting (syncope)
- Severe abdominal pain (may be caused by inflammation of the pancreas)
- Jaundice (yellowing of the skin or eyes)
- If you get a rash which looks like targets, blisters, skin peeling off in sheets, which may appear also on the lips, eyes, mouth, nose and/or genitals. You may also have a high temperature or joint pain (erythema multiforme)
- If you get severe skin reaction of which symptoms may be reddening of the skin, skin scaling, blistering or raw sores, detachment of the top layer of the skin from bottom layers ('Steven-Johnson Syndrome', 'toxic epidermal necrolysis')

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to ENALAPRIL UNIMED. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

Frequent side effects :

- chest pain
- heart attack (myocardial infarction), stroke (cerebrovascular accident)
- angina pectoris (squeezing, heaviness or pain in the chest caused by decreased blood flow to the muscles of the heart)
- difficulty breathing

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- increased blood potassium level, increased levels of creatinine in your blood (both are usually detected by a test).

Less frequent side effects :

- vertigo (spinning sensation)
- Blood disorders which affect the cells or elements in the blood and are usually diagnosed by blood tests (symptoms may be tiredness, weakness, shortness of breath, inability to exercise, feeling run down, having constant or re-occurring colds, fever, chills, prolonged bleeding, bruising where cause is unknown, red or purple spots)
- decreased red blood cells (bone marrow depression) picked up by a blood test
- swollen glands in neck, armpit or groin.
- changes in the way your heart beats, for example if you notice it beating faster (palpitations)
- sudden fall in blood pressure (hypotension)
- a bloating feeling and cramping pain in the abdomen (may be caused by an obstruction of the gut)
- lower back pain and reduction in the volume of urine passed (this may indicate reduced kidney function or kidney failure)
- high level of proteins in the urine (usually detected by a blood test).
- high level of blood urea, low level of sodium, high levels of liver enzymes and serum bilirubin (all measured in a blood test)

These are all serious side effects. You may need urgent medical attention.

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Tell your doctor if you notice any of the following:

Frequent side effects :

- headache
- depression
- blurred vision
- cough
- feeling sick (nausea)
- diarrhoea
- pain around your stomach area (abdominal pain)
- change in sense of taste
- weakness
- tiredness (fatigue)
- rash.

Less Frequent side effects :

- tiredness (which may be due to anaemia or decrease in haemoglobin)
- low blood sugar which may cause you to feel shaky
- sleepiness
- pins and needles
- confusion and nervousness
- insomnia, abnormal dreams, sleep disorders
- small arteries, usually in the fingers and toes, go into spasm causing the skin to become pale or patchy red to blue colour and very cold- ('Raynaud's phenomenon')
- flushing
- runny nose and hayfever

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- sore throat and hoarseness
- wheeze when you breathe (asthma)
- inflammation of your nose
- pneumonia (signs may be cough, high temperature and difficulty breathing)
- vomiting, indigestion
- constipation, loss of appetite
- stomach irritation, dry mouth
- symptoms may be burning, aching pain with an empty feeling and hunger, particularly when the stomach is empty (peptic ulcer)
- pain, inflammation and/or ulceration of the gums, cheeks, tongue, lips, throat
- excessive sweating
- hair loss
- difficulty getting an erection (impotence)
- enlargement of breasts in men
- muscle cramps and inflammation
- ringing in the ears (tinnitus)
- fever and generally feeling unwell.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of ENALAPRIL UNIMED.

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5. How to store ENALAPRIL UNIMED

Store at or below 25 °C.

Protect from light.

Do not remove blisters from the carton until required for use.

Do not use the medication after the expiry date printed on the container.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets)

STORE ALL MEDICINE OUT OF REACH OF CHILDREN.

6. Contents of the pack and other information

What ENALAPRIL UNIMED contains

The active substance is Enalapril Maleate.

The other ingredients are:

ENALAPRIL 2,5 & 5 mg UNIMED	ENALAPRIL 10 & 20 mg UNIMED
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Starch Pregelatinized	Starch Pregelatinized
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Maize starch	Maize starch
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Sodium bicarbonate	Sodium bicarbonate
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Lactose monohydrate	Lactose monohydrate
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Magnesium stearate	Ferric Oxide
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	Magnesium stearate
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What ENALAPRIL UNIMED looks like and contents of the pack

ENALAPRIL 2,5 mg UNIMED:

White, round, biconvex tablet, plain on both sides, 6 mm in diameter.

ENALAPRIL 5 mg UNIMED:

White, oval, biconvex tablet, plain on both sides, 11 mm long and 6 mm

wide. **ENALAPRIL 10 mg UNIMED:**

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Rusty red, oval, biconvex tablets, plain on both sides, 11 mm long and 6 mm wide.

ENALAPRIL 20 mg UNIMED:

Peach, oval, biconvex tablets, plain on both sides, 11 mm long and 6 mm wide.

Packed in blister packs of 10, 14, 28 or 30 tablets of each strength and high density polyethylene containers or amber glass bottles of 30, 50, 56, 100 or 500 tablets of each strength.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Unimed Healthcare (Pty) Ltd

Corner Birch Road and Bluegum Avenue

Anchorville

Lenasia

1827

South Africa

This leaflet was last revised in

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ENALAPRIL 10 mg UNIMED: 35/7.1.3/0053

ENALAPRIL 20 mg UNIMED: 35/7.1.3/0054