

PATIENT INFORMATION LEAFLET

ENAP RANGE

SCHEDULING STATUS

S3

ENAP 5 mg tablets

ENAP 10 mg tablets

ENAP 20 mg tablets

Enalapril maleate

ENAP contains sugar (lactose monohydrate 129,80 mg, 124,60 mg and 117,80 mg in ENAP 5 mg, 10 mg and 20 mg respectively).

Read all of this leaflet carefully before you start taking ENAP

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- ENAP has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What ENAP is and what it is used for

Enalapril belongs to a class of medicines called ACE inhibitors.

ENAP is used to treat hypertension (high blood pressure) or heart failure (weakening of heart

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function). ENAP is also used for the prevention of symptomatic heart failure.

2. What you need to know before you take ENAP

Do not take ENAP:

- if you are hypersensitive (allergic) to enalapril, or to any of the ingredients of ENAP (see section 6)
- if you are taking fluoroquinolones (type of antibiotic) such as ciprofloxacin or levofloxacin with ENAP, contact your doctor to re-evaluate your treatment
- if you have previously been treated with medicines of the same type as ENAP and have experienced allergic reactions with difficulties of breathing or swallowing, swelling of hands, feet or ankles, or if you or your family have had this reaction due to other reasons. You must never take these medicines (including ENAP) again
- if you have hereditary angioedema (a condition that makes you more prone to the swelling described above)
- if you have an increase in the thickness of the heart muscle (known as hypertrophic cardiomyopathy)
- if you have severe kidney problems
- if you have a narrowing (stenosis) of the aorta (an artery from your heart) or the kidney artery
- if you are already taking potassium sparing water tablets which contain eplerenone, spironolactone, triamterene or amiloride (used to treat fluid retention in patients with high blood pressure, heart, liver or kidney problems)
- if you suffer from porphyria (a rare blood disorder)
- if you are not passing urine
- if you have severe liver problems
- if you are taking lithium (used to treat depression or mood disorders)
- if you are pregnant or breastfeeding your baby (see Pregnancy and breastfeeding)

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- if you are simultaneously using aliskiren (medication used for treatment of high blood pressure), see Other medicines with ENAP.

Warnings and precautions

Take special care with ENAP:

Should you become pregnant while receiving ENAP, this medicine must be stopped immediately and switched to different type of hypertension medicine. Consult your doctor if you are contemplating pregnancy.

- if you are currently on any fluoroquinolones, such as ciprofloxacin or levofloxacin, as the concomitant use of fluoroquinolone and angiotensin receptor blockers such as ENAP may cause acute kidney injury, contact your doctor to re-evaluate your treatment
- 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 have heart problems
- if you have kidney problems, have recently had a kidney transplant or you are having kidney dialysis
- if you are taking immunosuppressant therapy (used to treat arthritis or following transplant surgery)
- if you are taking procainamide (for treatment of abnormal heart rhythms) or allopurinol (for gout)
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- if you have diabetes; your need for insulin and other treatments against diabetes may be altered
- if you have a history of 'angioedema" (a severe allergic reaction) to medicines
- if you are about to undergo desensitization therapy due to an allergy against bee or wasp stings
- if you are about to receive a treatment called LDL apheresis, which removes cholesterol from your blood using a machine
- if you have upper respiratory tract infections, such as a cough
- if you have liver problems or have been told you suffer from a blood disorder
- if you are taking potassium-sparing diuretics (water tablets such as eplerenone, spironolactone (potassium supplements and/or potassium-containing salt substitutes), triamterene or amiloride) and certain other diuretics, which could result in high potassium blood levels (common symptoms are vague feeling of discomfort/ feeling bad, palpitations and muscle weakness)
- if you are going to have surgery or be given an anaesthetic. You must tell your doctor before you take ENAP
- if you suffer from low blood pressure. You may notice this as feeling dizzy or light-headed, especially when standing up
- if your ethnic group is black, as you may be at an increased risk of having an allergic reaction to ENAP, this medicine may not work as well for you as for other ethnic groups.

Other medicines and ENAP

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

ENAP can interact with the following medicines:

- Angiotensin II receptor blocker (ARB) (also known as sartans - for example valsartan, telmisartan, irbesartan) or aliskiren

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- fluoroquinolones (type of antibiotic) such as ciprofloxacin or levofloxacin may lead to acute kidney injury, contact your doctor to re-evaluate your treatment
- sacubitril/valsartan (used to treat heart failure), antidiarrheal (e.g. racecadotril) and mTOR inhibitors (used in the treatment of renal cancer, e.g. sirolimus, everolimus, / temsirolimus) and vildagliptin (used to treat diabetes) may lead to an increase risk of angioedema
- lithium used to treat depression or mood disorders (see Do not take ENAP)
- water tablets (diuretics) or other blood pressure lowering medicines
- tricyclic antidepressants used for depression, antipsychotics used for severe anxiety
- injectable gold (sodium aurothiomalate) an injectable medicine used to treat stiffness and inflammation in muscles, bones and joints
- medicines such as adrenaline (epinephrine), noradrenaline (norepinephrine) used in some cough and cold remedies or noradrenaline (norepinephrine) and adrenaline (epinephrine) used for low blood pressure, shock, heart failure, asthma and allergies
- medicines used to treat diabetes (e.g. metformin, insulin and diazoxide)
- nonsteroidal anti-inflammatory medicines (NSAIDs) including aspirin and ibuprofen, and COX-2-inhibitors, e.g. celecoxib (used to treat pain and inflammation)
- medicines used for arthritis or gout (allopurinol, cytostatic or immune-suppressive agents, systemic corticosteroids)
- ciclosporin (medicine used for organ transplant, arthritis or psoriasis).

ENAP with food, drink and alcohol

ENAP can be taken before, with or after food

ENAP taken together with alcohol may cause dizziness or light-headedness.

Pregnancy, breastfeeding and fertility

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If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before using ENAP.

You must not take ENAP if you are pregnant or breastfeeding.

ENAP can cause harm to your unborn baby. If you are pregnant, become pregnant or plan on becoming while taking this medicine, stop taking the tablets and talk to your doctor immediately, who will change you to another medicine.

Driving and using machines

Medicines which lower blood pressure may cause dizziness or drowsiness. Please make sure you know how ENAP affects you before driving or using machinery.

It is not always possible to predict to what extent ENAP may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which ENAP affects them.

ENAP contains lactose

Patients with the rare hereditary conditions of lactose or galactose intolerance should not take ENAP.

3. How to take ENAP

Do not share medicines prescribed for you with any other person. Always use ENAP exactly as your doctor has told you. You should check with your doctor or pharmacist if you are unsure.

Adults:

High blood pressure:

The usual starting dose is 10 mg to 20 mg taken once daily. Some patients may need a lower starting dose. The usual long term dose is 20 mg taken once daily.

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Heart failure:

The usual starting dose is 2,5 mg taken once daily. Your doctor will gradually increase the dose to the right amount for you. The usual long term dose is 20 mg taken once daily.

Take special care when taking your first dose of ENAP, or if your dose is increased. You may feel light-headed or dizzy; let your doctor know if you experience these symptoms.

Children:

ENAP should not be given to children or adolescents under the age of 18 years.

Your doctor will tell you how long your treatment with ENAP will last. Do not stop treatment early because your high blood pressure may return.

If you have the impression that the effect of ENAP is too strong or too weak, tell your doctor or pharmacist.

If you take more ENAP than you should

In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

Symptoms of overdose may include:

- stupor (a state of almost complete lack of consciousness), light-headedness or dizziness, very slow, fast or irregular heartbeat and pulse, anxiety and cough.

If you forget to take ENAP

If you forget to take ENAP, take as soon as you remember on the same day. If you do not take a tablet that same day, take your normal dose the next day. Do not take a double dose to make up for forgotten individual doses.

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If you stop taking ENAP

This medicine helps control high blood pressure. You may have to take high blood pressure medicine for the rest of your life. If high blood pressure is not treated, it can cause serious problems such as heart failure, blood vessel disease, stroke or kidney disease.

4. Possible side effects

ENAP can have side effects.

Not all side effects reported for ENAP are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while using ENAP, please consult your healthcare provider for advice.

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

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to ENAP. 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:

- heart attack or stroke
- chest pain, heart rhythm changes, angina
- liver failure, this may cause yellowing of the skin (jaundice), inflammation liver (hepatitis)
- inflammation of the pancreas (pancreatitis)
- Stevens-Johnson syndrome and toxic epidermal necrolysis (severe skin conditions with

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reddening, scaling and blistering of the skin)

- eruption of lesions on the skin or mouth known as erythema multiforme that have a pink-red centre surrounded by a pale ring border and an outer pink-red ring. The lesions can sometimes be painful or itchy
- kidney problems such as lower back pain and reduction in the amount of urine which you pass, kidney failure
- pemphigus, a skin disease in which watery blisters form on the skin, skin peeling off in sheets (exfoliative dermatitis)
- blood disorders which can make the skin pale and cause breathlessness, weakness, bruising, an increased the risk of bleeding or make infections more likely
- electrolyte imbalances, including low blood levels of sodium (hyponatraemia) or low or high levels of potassium (hyperkalaemia) in the blood which can cause tiredness, confusion, and fits (convulsion)
- inflammation of the lungs (allergic alveolitis or eosinophilic pneumonia) due to an allergic reaction causing excessive fluid accumulation in lungs (pulmonary infiltrates) with symptoms such as breathlessness, wheezing, cough, chest tightness and difficulty in breathing.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- depression
- blurred vision
- feeling dizzy or light-headed, especially if you stand up quickly
- cough, shortness of breath
- pain around your stomach area (abdomen), diarrhoea, feeling sick

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- rash
- loss of strength and fatigue
- increased levels of creatinine in your blood (detected by a test).

Less frequent side effects:

- autoimmune diseases (diseases in which the body's immune system attacks healthy cells), bone marrow depression, lower-than-normal number of red and white blood cells and platelets in the blood, swelling of the lymph glands
- overproduction of antidiuretic hormone, which causes fluid retention, resulting in weakness, tiredness or confusion called syndrome of inappropriate antidiuretic hormone secretion (SIADH)
- low levels of blood sugar (hypoglycaemia)
- confusion, strange dreams, difficulty sleeping, feeling nervous, "pins and needles", drowsiness, spinning feeling (vertigo)
- ringing in the ears (tinnitus)
- fast heartbeat, flushing, low blood flow to your fingers and toes causing redness and pain (Raynaud's phenomenon)
- difficulty breathing, asthma, runny or blocked nose, sore throat and hoarseness
- anorexia, constipation, indigestion, infection or pain and swelling of your tongue, a blockage in your intestine (ileus), intestinal 'angioedema' (signs may include stomach pain, feeling sick and vomiting), swelling or ulcers in your mouth, being sick, dry mouth, stomach ulcer
- hair loss, excessive sweating, excessive itchiness or redness of your skin, hives, sensitivity of the skin to sunlight
- muscle cramps
- impotence and development of breasts in males

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- feeling extremely tired or weak, fever
- abnormal kidney and liver test results.

A complex side effect has been reported which may include some or all of the following signs:

- fever, pain and inflammation of the muscle or joints, rash, hypersensitivity to sunlight and other effects on the skin.

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, pharmacist or nurse. You can also report any side effects to SAHPRA via the online service for adverse drug reaction reporting by using either of the following links: <https://www.sahpra.org.za/Publications/Index/8> or

<https://www.sahpra.org.za/document/adverse-drug-reactions-and-quality-problem-reporting-form/>.

By reporting side effects, you can help provide more information on the safety of ENAP.

You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za, to ensure safety of the product.

5. How to store ENAP

Store all medicines out of reach of children.

Store in a dry place at or below 25 °C.

Protect from light.

Keep blisters in carton until required for use.

Do not use after the expiry date stated on the carton.

Return all unused medicine to your pharmacist.

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

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6. Contents of the pack and other information

What ENAP contains:

The active ingredient is enalapril maleate.

ENAP 5 mg: Each tablet contains 5 mg enalapril maleate.

ENAP 10 mg: Each tablet contains 10 mg enalapril maleate.

ENAP 20 mg: Each tablet contains 20 mg enalapril maleate.

The other ingredients are:

Hydroxypropyl cellulose (5 mg tablet only), iron oxide red (10 mg and 20 mg tablets only), iron oxide yellow (20 mg tablets only) lactose monohydrate, magnesium stearate, maize starch, sodium hydrogen carbonate, talc.

What ENAP looks like and contents of the pack

ENAP 5 mg: Round, flat, white tablets, bevel-edged, scored on one side.

ENAP 10 mg: Round, flat, red-brown tablets, bevel-edged, scored on one side, with individual white spots.

ENAP 20 mg: Round, flat, light orange tablets, bevel-edged, scored on one side, with individual white spots.

Blister strips of 30 tablets are packed, with a leaflet, in a printed outer carton.

Holder of Certificate of Registration

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This leaflet was last revised in

15 September 2023

Registration number

ENAP 5 mg: A34/7.1.3/0085

ENAP 10 mg: A34/7.1.3/0086

ENAP 20 mg: A34/7.1.3/0087

NAMIBIA:

ENAP 5 mg: NS2 04/7.1.3/1138

ENAP 10 mg: NS2 04/7.1.3/1137

ENAP 20 mg: NS2 04/7.1.3/1136

BOTSWANA:

ENAP 5 mg: BOT S2 0701085

ENAP 10 mg: BOT S2 0801495

ENAP 20 mg: BOT S2 0701086

MOZAMBIQUE:

ENAP 5 mg: 4273

ENAP 10 mg: 4274

ENAP 20 mg: 4275