

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S3

PROPRIETARY NAME AND DOSAGE FORM:

ENAP 5 mg tablets

ENAP 10 mg tablets

ENAP 20 mg tablets

Read all of this leaflet carefully before you start taking ENAP.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- **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.

1. WHAT ENAP CONTAINS:

The active substance is enalapril maleate.

The other ingredients are hydroxypropyl cellulose (5 mg tablet only), lactose monohydrate, magnesium stearate, maize starch, sodium hydrogen carbonate, talc.

The following colourants are also included; iron oxide red (10 mg and 20 mg tablets only), iron oxide yellow (20 mg tablets only).

ENAP contains lactose (see **BEFORE YOU TAKE ENAP**).

2. WHAT ENAP IS USED FOR:

ENAP is used to treat hypertension (high blood pressure) or heart failure (weakening of heart function). **ENAP** is also used for the prevention of symptomatic heart failure.

3. BEFORE YOU TAKE ENAP:

Do not take ENAP if:

- if you are hypersensitive (allergic) to enalapril maleate or any of the other ingredients of **ENAP** (see **WHAT ENAP CONTAINS**).
- if you are taking fluoroquinolones (type of antibiotic) such as ciprofloxacin or levofloxacin with **ENAP**, contact your doctor to re-evaluate your treatment.
- 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.
- 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).
- You have severe kidney or liver problems.
- You have a narrowing (stenosis) of the aorta (an artery from your heart) or the kidney artery.
- 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).
- You suffer from porphyria (a rare blood disorder).
- You are not passing urine.

- You have severe liver problems.
 - 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 **Taking other medicines with ENAP**.

Take special care with ENAP:

- 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 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).
- 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.

Taking ENAP with food and drink:

ENAP can be taken before, with or after food.

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

Pregnancy and breastfeeding:

If you are pregnant or planning to become pregnant or breastfeeding your baby, please consult your healthcare provider for advice before taking **ENAP**.

Driving and machinery:

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

Important information about some of the ingredients of ENAP:

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

ENAP contains lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

Taking other medicines with 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:

- 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**).
- Potassium supplements, potassium sparing water tablets e.g. eplerenone, spironolactone, triamterene or amiloride) or potassium-containing salt substitutes.
- 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 epinephrine, norepinephrine use in some cough and cold remedies or noradrenaline and adrenaline used for low blood pressure, shock, heart failure, asthma and allergies.
- medicines used to treat diabetes (e.g. metformin, insulin and diazoxide).
- non-steroidal anti-inflammatory medicines (NSAIDs) including aspirin (used to treat pain and inflammation).

HOW TO TAKE ENAP:

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

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.

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.

Always take **ENAP** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

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

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

If you take more ENAP than you should:

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

You may experience the following side-effects if you take an overdose of **ENAP**: 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 an **ENAP** tablet, take it 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 a forgotten dose.

5. 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 doctor, pharmacist or other health care professional for advice.

If any of the following happens, stop taking **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.

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.

You should be aware that black patients are at a greater risk of the above reactions.

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

These are all serious side effects which are frequent in patients who already have a heart disorder or disease of the blood vessels (especially arteries). You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- depression
- headache, changes in taste
- blurred vision

- feeling dizzy or light-headed, especially if you stand up quickly, fainting
- cough, shortness of breath
- pain around your stomach area (abdomen), diarrhoea, feeling sick.
- Loss of strength and fatigue

The following side-effects are less frequent:

- 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 and dry mouth
- liver failure, this may cause yellowing of the skin (jaundice)
- hair loss, excessive sweating, excessive itchiness or redness of your skin, blisters, skin peeling off in sheets
- muscle cramps
- kidney problems such as lower back pain and reduction in the amount of urine which you pass and protein in the urine
- impotence and development of breasts in males
- feeling extremely tired or weak

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 any of the above side effects not mentioned in this leaflet, please inform your doctor or pharmacist

6. STORING AND DISPOSING OF ENAP:

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

Keep the blisters in the carton until required for use.

STORE ALL MEDICINE OUT OF REACH AND SIGHT OF CHILDREN.

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)