

PATIENT INFORMATION LEAFLET**ENAP-CO****SCHEDULING STATUS:** S3**PROPRIETARY NAME, STRENGTH AND DOSAGE FORM:****ENAP-CO** tablets**Read all of this leaflet carefully before you start taking ENAP-CO.**

- Keep this leaflet. You may need to read it again.
- If you have further questions please ask your doctor or your pharmacist.
- **ENAP-CO** 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-CO CONTAINS:

The active substances are enalapril maleate and hydrochlorothiazide.

Each **ENAP-CO** tablet contains 20 mg enalapril maleate and 12,5 mg hydrochlorothiazide.

The other ingredients are lactose monohydrate, magnesium stearate, maize starch, pre-gelatinised starch, sodium hydrogen carbonate, talc.

ENAP-CO contains sugar (lactose monohydrate 122,16 mg).

2. WHAT ENAP-CO IS USED FOR:

ENAP-CO is used to treat hypertension (high blood pressure). Your doctor will usually prescribe **ENAP-CO** when your blood pressure has already been controlled after taking both the individual active ingredients of this medicine separately.

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- **You are pregnant, think you may be pregnant, plan to become pregnant or are breastfeeding. A different medicine should be taken if you are planning a pregnancy.**
- You are allergic (hypersensitive) to enalapril, hydrochlorothizide or any of the ingredients in this medicine (see **WHAT ENAP-CO CONTAINS**), or if you are hypersensitive to a type of medicine called “sulphonamide” which is used to treat infections.
- If you are taking fluoroquinolones (type of antibiotic) such as ciprofloxacin or levofloxacin with **ENAP-CO**, contact your doctor to re-evaluate your treatment.
- You have previously been treated with medicines of the same type as **ENAP-CO** 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-CO**, again.
- You have hereditary angioedema (a condition that makes you more prone to the swelling described above).
- You have an increase in the thickness of the heart muscle (known as hypertrophic cardiomyopathy).
- You have severe kidney problems (e.g. you are not passing urine).
- You have a narrowing of the blood vessels to both kidneys or to a single kidney.
- You have aortic stenosis, a narrowing of the aortic valve opening between the left ventricle (large pumping chamber of the heart) and the aorta (the main artery leading away from the heart).

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- 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 taking lithium (used to treat depression or mood disorders).
- You are taking aliskiren-containing products (to treat high blood pressure).

Take special care with ENAP-CO:

Before you take **ENAP-CO** you must inform your pharmacist or doctor if:

- You are pregnant or think you may be pregnant. You must not take **ENAP-CO** (see **Pregnancy and breastfeeding**)
- If you are taking fluoroquinolones (type of antibiotic) such as ciprofloxacin or levofloxacin with **ENAP-CO**, contact your doctor to re-evaluate your treatment.
- Your body lacks salt due to a low salt diet, or you have recently lost a lot of body fluids through taking strong water tablets (diuretics), or due to vomiting or diarrhoea.
- You are taking potassium supplements or potassium containing salt substitutes.
- You have kidney problems, have recently had a kidney transplant or you are having kidney dialysis.
- You have heart problems.
- You suffer from low blood pressure. You may notice this as feeling dizzy or light-headed, especially when standing up.
- You have collagen vascular disease (a disease which affects the connective tissue which forms the support system for your body).

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- You are taking immunosuppressant therapy (used to treat arthritis or following transplant surgery).
- You are taking procainamide (for treatment of abnormal heart rhythms) or allopurinol (for gout).
- You develop an infection (symptoms may be high temperature or fever).
- You have diabetes; your need for insulin and other treatment against diabetes may be altered. You should monitor your blood for low blood glucose levels, especially during the first month of treatment.
- You have a history of angioedema (a severe allergic reaction) to medicines. The signs may be itching, rash, wheezing or swelling of your hands, throat, mouth or eyelids.
- if you had skin cancer or if you develop an unexpected skin lesion (unusual growth of skin). Treatment with hydrochlorothiazide as in **ENAP-CO**, particularly long term use with high doses, may increase the risk of some types of skin and lip cancer (non-melanoma skin cancer). Protect your skin from sun exposure and UV rays while taking **ENAP-CO**.
- You are about to undergo desensitization therapy due to allergy against bee or wasp stings.
- You are about to receive a treatment called LDL apheresis, which removes cholesterol from your blood using a machine.
- You experience coughing.
- You are going to have surgery or be given an anaesthetic. You must tell your doctor before you take **ENAP-CO** since you may experience a sudden drop in blood pressure.

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- You have liver problems

DO NOT give **ENAP-CO** to adolescents and children younger than 18 years as safety and efficacy have not been established.

Routine tests:

When you first start to take **ENAP-CO**, your doctor will monitor your blood pressure frequently to ensure you have been given the correct dose. In addition, for some patients the doctor may want to do some tests to measure your potassium, sodium, magnesium, creatinine and liver enzyme levels. Your doctor may also check your kidney function.

Taking ENAP-CO with food and drink:

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

Pregnancy and breastfeeding:

DO NOT take **ENAP-CO** if you are pregnant, plan to become pregnant, or think that you are pregnant. Contact your healthcare provider immediately.

DO NOT take **ENAP-CO** during breastfeeding.

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

Driving and using machinery:

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

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

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

Taking other medicines with ENAP-CO:

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

ENAP-CO 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
- Other ACE inhibitors or aliskiren (used to treat high blood pressure) or angiotensin II receptor blockers (ARBs) also known as sartans e.g. valsartan, telmisartan, irbesartan etc.
- Other medicines used to treat high blood pressure such as nitroglycerine, nitrates and vasodilators.
- Lithium used to treat depression or mood disorders (see **Do not take ENAP-CO**).
- Non-steroidal anti-inflammatory medicines (NSAIDs) including aspirin (used to treat pain and inflammation).
- Potassium sparing water tablets (diuretics) such as eplerenone, spironolactone, triamterene or amiloride), potassium supplements or potassium-containing salt substitutes.
- Water tablets (diuretics) e.g. thiazides, furosemide, bumetanide.

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- Tricyclic antidepressants used for depression, antipsychotics used for severe anxiety or anaesthetics.
- Injectable gold (sodium aurothiomalate) an injectable medicine used to treat stiffness and inflammation in muscles, bones and joints.
- Medicines such as epinephrine, used in some cough and cold remedies or noradrenaline and adrenaline used for low blood pressure, shock, heart failure, asthma or allergies.
- Medicines used to treat diabetes (e.g. insulin).
- Muscle relaxants (e.g. tubocurarine).
- Barbiturates (sedatives used for sleepiness or epilepsy).
- Cholestyramine and colestipol (used to help control cholesterol levels).
- Quinidine, procainamide, amiodarone or sotalol (used to treat abnormal heart rhythms).
- Digoxin (used to treat heart rhythm problems).
- Corticosteroids (therapy for certain conditions such as rheumatism, arthritis, allergies, asthma or certain blood disorders).
- ACTH (to test whether your adrenal glands are working properly).
- Carbenoxolone (used to treat stomach ulcers).
- Excessive use of laxatives.
- Medicines for the treatment of cancer (e.g. methotrexate, cyclophosphamide).

HOW TO TAKE ENAP-CO:

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

Always take **ENAP-CO** exactly as your doctor has instructed you. You should check

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with your doctor or pharmacist if you are unsure.

The usual dose is one tablet taken once a day. Your doctor may increase the dose to two tablets taken once a day.

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

If you have kidney problems, consult your doctor for the appropriate dosage of **ENAP-CO**.

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

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

If you take more ENAP-CO 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-CO**: stupor (a state of almost complete lack of consciousness), light-headedness or dizziness, very slow, fast or irregular heartbeat and pulse, anxiety, cough and shortness of breath.

If you forget to take a dose of ENAP-CO:

If you forget to take a **ENAP-CO** 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.

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ENAP-CO can have side effects.

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

If any of the following happens, stop taking **ENAP-CO** 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.
- a rash or itching.

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

- changes to your heart function, signs of which may include the following; chest pain, irregular or rapid heart rate, heart attack or stroke (in high risk patients),
- liver failure which may cause yellowing of the skin (jaundice)
- Stevens-Johnson syndrome and toxic epidermal necrolysis (severe skin conditions with reddening, scaling and blistering of the skin)
- kidney problems such as lower back pain and reduction in the amount of urine which you pass

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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:

- dizziness
- blurred vision
- feeling light-headed, low blood pressure (which may make you feel dizzy when you stand up), fainting
- depression
- cough
- feeling or being sick, diarrhoea, change in taste, vomiting
- muscle cramps
- impotence
- feeling extremely tired or weak

Less frequent side effects:

- you may feel unwell due to changes to the content or your blood; your doctor will usually detect these changes in a blood test.
- gout (a type of arthritis, which often starts in the big toe)
- decreased sex drive
- problems sleeping, pins and needles, headache, nervousness, sleepiness, vertigo (spinning sensation), confusion, abnormal dreams, restlessness
- ringing in the ears (tinnitus)
- low blood flow to your fingers and toes causing redness and pain (Raynaud's

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phenomenon)

- shortness of breath, difficulty breathing or asthma, accumulation of fluid or other substances in the lungs (seen on X-rays), runny or sore throat and hoarseness
- dry mouth, wind, indigestion, pain around your stomach area, constipation, swollen and tender stomach, changes in taste, inflammation of the tongue, a blockage in the intestine, pain, swelling or ulcers in the mouth
- rash, excessive sweating, excessive itchiness or redness of your skin, severe hypersensitivity reaction with high fever, skin rash that looks like targets, severe skin rash with loss of skin and hair, small fluid-filled bumps on the skin, sensitivity of the skin to sunlight
- muscle or joint pain
- flushing.

Frequency unknown side effects:

- skin and lip cancer (non-melanoma skin cancer), with abnormal growth of skin, bump or sores on the lips that persist for a long period of time
- overproduction of antidiuretic hormone, which causes fluid retention, resulting in weakness, tiredness or confusion.
- anorexia.

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

6. STORING AND DISPOSING OF ENAP-CO:

Store all medicines out of reach of children.

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

Protect from light.

Keep the 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).