

PATIENT INFORMATION LEAFLET FOR ENAP-CO

SCHEDULING STATUS

S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

ENAP-CO (tablets)

Please read this leaflet carefully before using ENAP-CO

- Keep this leaflet. You may need to read it again.
- If you have any 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

Active ingredients:

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

2. WHAT ENAP-CO IS USED FOR

ENAP is used to treat hypertension (high blood pressure)

3. BEFORE YOU USE ENAP-CO

Do not take ENAP-CO:

- If you are allergic (hypersensitive) to enalapril or hydrochlorothiazide (see **WHAT ENAP-CO CONTAINS**)
- If you have a history of swelling of the face, lips, tongue, extremities or throat (allergic reaction) relating to the treatment with a similar blood pressure tablet (ACE-inhibitor), or other sulphonamide-derived medicines.
- If you have anuria (kidneys are not able to produce urine)
- If you are pregnant or breastfeeding your baby (see **Pregnancy and Breastfeeding and Take special care with ENAP-CO**)

Take special care with ENAP-CO:

- If you become pregnant whilst taking **ENAP-CO**, the medication must be stopped and your doctor will switch your medicine to a different type of medicine (see **Do not take ENAP-CO and Pregnancy and Breastfeeding**)
- Inform your doctor if you plan to become pregnant, before you are given **ENAP-CO** so that the doctor may prescribe another type of medicine. **ENAP-CO** may harm your baby and cause deformities especially during the 2nd and 3rd trimesters of your pregnancy. Prematurity and low birth mass may also occur.
- If you have other heart problems, or used a water tablet prior treatment with **ENAP-CO**, you may experience a serious fall in blood pressure.
- If you have liver or kidney problems
- If you experience abnormal blood test results during treatment, your doctor may want to withdraw your treatment

- Anaphylactoid reactions during Hymenoptera Desensitization (if you receive therapy to stimulate the immune system with insect venom, whilst taking **ENAP-CO**, you may experience life threatening reactions)
- If you experience swelling of the face lips, tongue and throat or find it difficult to breathe, you should stop taking **ENAP-CO** immediately (see **SIDE EFFECTS**), or have a history of allergic reactions (see **CONTRA-INDICATIONS**)
- If you receive dialysis – your doctor may want to give you a different class of medicine
- If you have liver disease
- If you have kidney problems (see **HOW TO USE ENAP-CO**)
- If you are scheduled for surgery or anaesthesia
- If you experience low blood pressure (feeling light headed or dizzy), contact your doctor, as he may want to reduce your dose or change your medication (see **Using other medicines with ENAP-CO** and **SIDE EFFECTS**)
- If you have diabetes or use insulin
- If you have gout, high cholesterol or thyroid problems

ENAP-CO should not be given to children.

Pregnancy and Breastfeeding:

Do not take **ENAP-CO** if you are pregnant, plan to become pregnant, or breastfeed your baby. (see **Do not take ENAP** and **Take special care with ENAP**).

Driving and using machinery:

ENAP-CO can cause dizziness or drowsiness in some patients which may affect your ability to drive and use machinery. You are therefore advised not to drive or use machinery until you are sure how **ENAP-CO** will affect you.

Using other medicines with ENAP-CO

Consult with your doctor or pharmacist or healthcare professional for advice if you need to take any other medicines. If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **ENAP** with these medicines may cause undesirable interactions.

The following medicine may interact with **ENAP**:

- Lithium (used for mood disorders) as **ENAP** may cause high blood levels of lithium
- If you are taking other blood pressure medicine with **ENAP**, such as water tablets (diuretics), beta blocking medicines and methyldopa or calcium blockers, **ENAP** may have a stronger effect
- If you have kidney problems or diabetes and use water tablets such as spironolactone, triamterene, or amiloride), or potassium supplements, your doctor may want to monitor your potassium levels regularly

4. HOW TO TAKE ENAP-CO

Hypertension (high blood pressure)

The usual dosage is one tablet, once a day. The doctor may increase the dosage to a maximum of two tablets, taken once a day, if necessary.

Renal insufficiency

ENAP-CO should not be used as initial therapy if you have renal insufficiency. Your doctor will however decide on the degree of kidney disease before treating you with **ENAP-CO**.

5. If you take more ENAP than you should:

In the event of an overdose, contact your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre as soon as possible. Take this leaflet and any remaining tablets with you, so that the doctor knows what you have taken.

Symptoms of overdose include low blood pressure and a lack of consciousness and commences approximately six hours after the ingestion of **ENAP**. Treatment may involve inducing vomiting or haemodialysis

6. If you forget to take your ENAP

Take the missed dose as soon as possible. However, if it is almost time for your next dose, continue to take the next tablet at the usual time. Do not take a double dose.

7. POSSIBLE SIDE-EFFECTS

ENAP may have side effects.

Not all side effects reported for **ENAP** are included in this leaflet.

Should your general health worsen while taking 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, lips, mouth or throat which may cause difficulty in breathing
- rash or itching
- jaundice (yellowing of the skin and eyes)

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 the casualty department at your nearest hospital if you notice any of the following:

- Heart attack, chest pain (angina), irregular or fast heartbeat
- Feeling dizzy when you get up (orthostatic hypotension)
- Hypotension (low blood pressure)
- Stevens Johnson syndrome (a serious skin condition with painful purplish rash and blisters)
- Confusion
- Depression and feeling tired
- Liver failure with symptoms such as swelling of your abdomen, vomiting and yellowing of your skin and eyes or other liver problems
- Asthma, difficulty in breathing or shortness of breath
- Inflammation of the pancreas with symptoms such as swollen and tender abdomen, fever, nausea and vomiting
- Kidney problems, kidney failure, producing less urine than normal

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

Tell your doctor if you notice any of the following:

- Dizziness, sleeplessness, nervousness, vertigo, drowsiness
- Headache, hair loss
- Nausea, vomiting, diarrhoea, constipation
- Muscle cramps, abdominal pain
- Indigestion, anorexia
- Inflammation of the mouth, tongue
- Cough, sore throat and hoarseness, runny nose
- Lung problems such as pneumonia
- Blurred vision
- Flushing, sweating
- Ringing in the ears, taste disturbances
- Inability to perform sexually
- A complex of conditions that may include fever, inflammation, arthritis, muscle cramps
- A feeling of pins and needles
- Skin conditions (rash, sensitivity to light, pemphigus, urticarial, erythema multiforme, exfoliative dermatitis)
- Abnormal blood tests

8. STORAGE AND DISPOSAL OF ENAP

Store in a dry place below 25 °C.

Do not remove tablets from the outer carton until required for use.

Protect from light.

KEEP OUT OF REACH OF CHILDREN.

Do not use after the expiry date printed on the label or carton.

Return all unused medicine to your pharmacist.

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

9. PRESENTATION OF ENAP

Available in blisters of 28 tablets.

10. IDENTIFICATION OF ENAP

ENAP 5 mg: A round, white bevelled edge tablet, scored on one side.

ENAP 10 mg: A round, flat, red brown, spotted tablet, with a bevelled edge and scored on one side.

ENAP 20 mg: A round, flat, light orange, spotted tablet, with a bevelled edge and scored on one side.

11. REGISTRATION NUMBER

ENAP 5 mg: 34/7.1.3/0085

ENAP 10 mg: 34/7.1.3/0086

ENAP 20 mg: 34/7.1.3/0087

12. NAME AND BUSINESS ADDRESS OF THE APPLICANT:

Pharma Dynamics (Pty) Ltd.

F02 Grapevine House,

Steenberg Office Park,

Westlake 7945

Cape Town

South Africa

13. DATE OF PUBLICATION

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