1.3.2. PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

PHARMAPRESS CO 20,0 mg/12,5 mg tablets

Enalpril; Hydrochlorothiazide

Contains sugar: Lactose monohydrate 130,50 mg

Read all of this leaflet carefully before you start taking PHARMAPRESS CO.

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

What is in this leaflet

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

1. What PHARMAPRESS CO is and what it is used for

PHARMAPRESS CO contains the active substances 20,0 mg enalapril maleate and 12,5 mg hydrochlorothiazide.

PHARMAPRESS CO belongs to a group of medicines called antihypertensives (medicines that lower your blood pressure).

PHARMAPRESS CO is indicated for the treatment of high blood pressure (hypertension) where fixed combination therapy is more appropriate than the two active substances separately (monotherapy).

The effect of these medicines is to lower your blood pressure. Taking both medicines that PHARMAPRESS CO contains can increase their effect compared to taking just one

What you need to know before you take PHARMAPRESS CO

Do not take PHARMAPRESS CO:

- if you are allergic hypersensitive (allergic) to enalapril maleate, hydrochlorothiazide, other thiazide diuretics or to other sulphonamide-derived medicines or to any of the ingredients of PHARMAPRESS CO (listed in section 6).
- if you suffer or have previously suffered from angioedema (swelling of the face, lips or tongue) due to a hereditary condition, an unknown cause or when previously taking certain medicines used to decrease blood pressure.
- if you have heart problems.
- if you have any kidney problems including kidney disease, impaired kidney function or are not passing urine.
- if you have liver problems or disease.
- if you are using potassium sparing diuretics (used to help lower blood pressure) such as spironolactone, triamterene or amiloride.

- if you have Addison's disease (a disorder in which the adrenal glands situated on top of your kidney do not produce enough hormones).
- if you are using lithium (used for the treatment of some psychiatric illnesses).
- if you are using aliskiren (medicine used to treat high blood pressure).
- if you have kidney problems and/or are elderly and you are taking medicine used to treat bacterial infections (antibiotics) belonging to the fluoroquinolone group. Contact your doctor to re-evaluate treatment if you are treated with PHARMAPRESS CO together with a fluoroquinolone antibiotic.
- if you are being treated with sacubitril/valsartan, a medicine for heart failure.
- if you have previously had or currently have cancer of the skin and/or lip.
- if you are pregnant or breastfeeding.

Warnings and precautions

Take special care with PHARMAPRESS CO:

- if you are taking diuretics (water tablets) or if you are dehydrated. Your doctor may advise that dehydration be corrected before you start taking PHARMAPRESS CO, this helps avoid symptoms of dizziness or light-headedness which are signs of low blood pressure, especially when you get up from a sitting or lying position.
- if you have fluid or electrolyte imbalances due to excessive sweating (perspiration), or if you are on a diet restricting the amount of salt that you take in daily, or if you are vomiting or have diarrhoea, etc. The electrolyte imbalance must be corrected before you start treatment with PHARMAPRESS CO. Warning signs of fluid or electrolyte imbalance are dry mouth, thirst, weakness, tiredness, sleepiness, restlessness, muscle pain or cramps, muscle tiredness, low blood pressure, reduced frequency of urination, fast heartbeat, nausea and vomiting. Your doctor may want to monitor the different levels of salt or electrolytes in your blood, especially if you have kidney

problems.

- if you are holding back fluid or have swelling in your feet, legs, arms or legs, especially in hot weather.
- if you are going to undergo surgery or if you are going to receive anaesthesia, you should tell your doctor that you are taking PHARMAPRESS CO.
- if you have diabetes mellitus (sugar diabetes) or if you have gout. These conditions may be made worse by PHARMAPRESS CO. You should monitor your blood sugar levels regularly.
- if you have high cholesterol (a type of fat in your blood).
- if your ethnic group is black, as you may be at an increased risk of having an allergic reaction to PHARMAPRESS CO and PHARMAPRESS CO might not work as well for you as for other ethnic groups.
- if you have systemic lupus erythematosus (an inflammatory disease caused when the immune system attacks its own tissues), scleroderma (chronic hardening and tightening of the skin and connective tissue) or rheumatoid arthritis (a chronic inflammatory disorder affecting many joints, including those in the hands and feet). PHARMAPRESS CO may make these conditions worse.
- if you develop a persistent and non-productive (without phlegm) cough while taking PHARMAPRESS CO. This cough resolves after stopping treatment.
- if you have had skin cancer or if you develop an unexpected skin lesion during the treatment with PHARMAPRESS CO. Treatment with PHARMAPRESS 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 PHARMAPRESS CO.
- if you have been stung by an insect and are receiving therapy, the use of PHARMAPRESS CO during therapy may cause life-threatening allergic reactions.

These reactions can be avoided by temporarily withholding PHARMAPRESS CO therapy before receiving therapy for the insect sting.

- if you are going to undergo an anti-doping test, as PHARMAPRESS CO can produce a false positive.
- if you are about to have any of the following procedures, you should tell your doctor who is treating you that you are taking PHARMAPRESS CO:

  - any surgery or receive anaesthetics (even at the dentist).
  - a treatment called LDL apheresis, to remove cholesterol from your blood using a machine.
  - desensitisation treatment, to reduce the effect of an allergy to bee or wasp stings.

- if you experience a decrease in vision or eye pain. These could be symptoms of fluid accumulation in the vascular layer of the eye (choroidal effusion) or an increase of pressure in your eye and can happen when using PHARMAPRESS CO. This can lead to permanent vision loss, if not treated. If you earlier have had a penicillin or sulfonamide allergy, you can be at higher risk of developing this.

Children

The safety and effectiveness of PHARMAPRESS CO have not been established in children.

Other medicines and PHARMAPRESS CO

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

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

- Antihypertensive medicines belonging to the angiotensin II receptor blocker (ARB) group (e.g. losartan, valsartan), medicine containing aliskiren, medicine belonging to the angiotensin converting enzyme group (ACE inhibitors) (e.g. captopril), diuretics (e.g. spironolactone, furosemide) and nitrates (e.g. nitroglycerine): other medicines used for the treatment of high blood pressure as it may add to the blood pressure lowering effects of PHARMAPRESS CO and increase the frequency of side effects.
- Antibiotics (fluoroquinolones e.g. ciprofloxacin, moxifloxacin, levofloxacin): medicine used to treat bacterial infections.
- Potassium supplements: medicine used to supplement the amount of potassium in your blood if you do not have enough.
- Heparin: medicine used to prevent blood clots. Heparin may increase the potassium level in your blood.
- Non-steroidal anti-inflammatory drugs (NSAIDs): Medicines used to treat pain, fever and inflammation. NSAIDs may interfere with the blood pressure lowering effects of PHARMAPRESS CO.
- Lithium: medicine used for the treatment of some mental diseases.
- Allopurinol: medicine used for the treatment of gout.
- Carbenoxolone: medicine used for the treatment of stomach or gut ulcers.
- Laxatives: medicine used to treat constipation.
- Tricyclic antidepressants (e.g. amitriptyline, nortriptyline): medicine used to treat depression.
- Antipsychotics: medicine used to treat mental disease.
- Anaesthetics: medicine used during operations to induce sleep and prevent pain.
- Gold: medicine used to treat rheumatoid arthritis.

- Mammaliam target of rapamycin inhibitors (e.g. temsirolimus, sirolimus, everolimus): medicine used to treat cancer or for the prevention of the rejection of an organ after an organ transplant.
- Antidiabetic medicines (e.g. insulin, metformin): medicine used in the treatment of diabetes to lower blood sugar (glucose) levels. PHARMAPRESS CO may decrease blood glucose concentrations. Dosage adjustment of the antidiabetic medicine may be necessary.
- Barbiturates (e.g. phenobarbitone, thiopental): medicine used to treat fits (epilepsy) or to induce sleep.
- Opioid analgesics (e.g. tramadol, pethidine, codeine): medicine used to treat pain.
- Cholestyramine and colestipol resins: medicine used to treat high cholesterol (fat in your blood).
- Anti-dysrhythmics (e.g. quinidine, procainamide, amiodarone, sotalol, digoxin): medicines used to treat heart rhythm problems.
- ACTH: Medicine used to test if you have problems with your adrenal gland, e.g. when you have Addison's disease, or to treat multiple sclerosis in adults and spasms in children.
- Corticosteroids: Medicines used as anti-inflammatory medicine and to prevent an immune response.
- Noradrenaline and adrenalin: Medicine used to treat low blood pressure in specific situations and serious allergic reactions.
- Cytostatics (e.g. cyclophosphamide, methotrexate): medicine used to treat cancer.
- Muscle relaxants (e.g. tubocurarine): medicine used to relax muscles during operations.
- A medicine containing a neprilysin inhibitor such as sacubitril (available as fixed-dose combination with valsartan) and racecadotril. The risk of angioedema (swelling of the

face, lips, tongue or throat with difficulty in swallowing or breathing) may be increased.

PHARMAPRESS CO with food and drink

PHARMAPRESS CO may be given at any time of the day, with or without food. No alcohol should be consumed during treatment with PHARMAPRESS CO, as it may worsen side effects.

Pregnancy, breastfeeding and fertility

You should not take PHARMAPRESS CO if you are pregnant or breastfeeding your baby.

Women of child-bearing potential should use an effective contraceptive during treatment with PHARMAPRESS CO.

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 healthcare provider for advice before taking PHARMAPRESS CO.

Driving and using machines

PHARMAPRESS CO has moderate influence on the ability to drive and use machines. Since adverse reactions such as tiredness, dizziness and blurred vision have been reported in patients receiving PHARMAPRESS CO, you should not drive, use machinery or perform any tasks that require concentration, until you are certain that PHARMAPRESS CO does not adversely affect your ability to do so (see Possible side effects).

It is not always possible to predict to what extent PHARMAPRESS CO 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 PHARMAPRESS CO affects them (see section 4).

PHARMAPRESS CO contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking PHARMAPRESS CO.

3. How to take PHARMAPRESS CO

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

Always take PHARMAPRESS CO exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

Your doctor will tell you how long your treatment with PHARMAPRESS CO will last.

Do not stop treatment early. If you have the impression that the effect of PHARMAPRESS CO is too strong or too weak, tell your doctor or pharmacist. Even if you feel better, do not stop taking PHARMAPRESS CO without talking to your doctor.

PHARMAPRESS CO may be taken alone or in combination with other medicines for high blood pressure.

Dosage

Adults: The usual dose of PHARMAPRESS CO is one tablet daily.

The dosage may be increased to a maximum of two tablets, given once daily, if appropriate.

In any patient with kidney problems (impairment), PHARMAPRESS CO must not be used as initial therapy.

If you take more PHARMAPRESS CO 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.

If you forget to take PHARMAPRESS CO

Do not take a double dose to make up for forgotten individual doses.

Take your missed dose as soon as you remember, if within a few hours after missing a dose.

If you stop using PHARMAPRESS CO

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

PHARMAPRESS CO can have side effects.

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

If any of the following happens, stop taking PHARMAPRESS 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, throat, glottis and/or larynx and or tongue, which may cause difficulty in swallowing or breathing,
- rash or itching,
- blistering of the skin, mouth, eyes and genitals as these may be due to a serious allergic reaction known as Stevens-Johnson Syndrome (SJS),
- eruption of lesions on the skin known as erythema multiforme,
- fever, flu-like symptoms, a painful red rash (may include purplish spots) that spreads, and blisters follows where the top part of the skin dies and peels off, known as toxic epidermal necrolysis (TEN),
- severe allergic reaction that has numerous symptoms including skin rash, fever, increased sensitivity to sunlight, swelling of glands, inflammation of blood vessels (vasculitis) and of the tissues lining the lungs, heart and stomach (with symptoms such as pain in the stomach, chest, joints or muscles) and abnormal blood results. This type of allergic reaction is known as drug rash with eosinophilia and systemic symptoms (DRESS),
- 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,
- malar eruption or 'butterfly rash' (erythema and oedema of cheeks, sparing nasolabial folds) lasting hours to days, as well as erythematous papular rash on arms, sometimes

forming large plaques and spreading widely. This may be cutaneous lupus erythematosus,

- pemphigus, a skin disease in which watery blisters form on the skin,

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to PHARMAPRESS CO. 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 problems including a heart attack, with symptoms such as abnormal, irregular, slow or fast heartbeat, heart rhythm changes, chest pain (angina pectoris) or tightness in the chest, neck, back or arms and anxiety,
- trouble walking, speaking and understanding as well as paralysis or numbness of the face, arm or leg as this may be symptoms of a stroke,
- inflammation of the pancreas (pancreatitis), liver (hepatitis) including death of liver tissue or failure of the liver, blockage of flow of bile from the liver (cholestasis) with symptoms such as severe pain in the stomach and back, nausea, vomiting and yellow pigmentation of skin and eyes (jaundice),
- blood disorders which can make the skin pale and cause breathlessness, weakness, bruising, an increased the risk of bleeding or make infections more likely,
- kidney problems, kidney failure and swelling and inflammation in between the kidney tubules with symptoms such as fever, blood in urine, protein in the urine (proteinuria), less urine than normal (oliguria) or no urine, exhaustion,
- 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),

- skin and lip cancer (skin cancer may be a sore that does not heal or comes back after healing, pale, white or yellow flat areas that look like scars, raised and scaly red patches, small, smooth and shiny lumps that are pearly white, pink or red, pink growths with raised edges and indents in the centre or growths that has small blood vessels on the surface) (non-melanoma skin cancer).

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, difficulty in sleeping (insomnia), headache,
- numbness, tingling, pins and needles, cold, warmth, tingling pressure of the skin (paraesthesia),
- decreased libido,
- severe dizziness, light-headedness, or fainting due to low blood pressure (hypotension) especially at the start of treatment, when your dose is increased or when you stand up,
- blurred vision,
- cough,
- feeling sick (nausea), vomiting, diarrhoea, stomach pain, changes in taste,
- increased sweating (diaphoresis),
- weakness or lack of energy and strength, tiredness,
- depression,
- muscle cramps,
- proteinuria is a condition characterized by the presence of greater than normal amounts of protein in the urine,
- blood tests or laboratory tests which shows changes in the way that the liver and

kidney is working,

- increased levels of uric acid in the blood that causes attacks of gout in some patients,
- increase in cholesterol and triglycerides in the body (body fats).

Less frequent side effects:

- loss of male sexual ability (impotence),
- muscular weakness due to low potassium levels,
- red, hot skin (flushing), an abnormal sensation, typically tingling or pricking ('pins and needles'),
- increase in body temperature (fever),
- increase in sweating,
- confusion, inability/ difficulty to sleep, nervousness, tiredness,
- feeling sleepy, feeling nervous (nervousness), feeling like you are spinning (vertigo), abnormal dreams, sleep abnormalities (disorders), dream abnormalities,
- ringing in the ears (tinnitus),
- indigestion (dyspepsia), constipation, dry mouth, flatulence, inability of the bowel to contract normally and move waste out of the body (ileus), stomach irritation, painful swelling and sores (aphtous ulcer) inside the mouth (stomatitis) or on the tongue (glossitis), swelling of the stomach,
- hair loss or baldness (alopecia),
- joint pain (arthralgia),
- autoimmune diseases (diseases in which the body's immune system attacks healthy cells),
- runny nose, sore throat, hoarseness,
- loss of appetite,

- burning, aching pain with an empty feeling and hunger, particularly when the stomach is empty (caused by a stomach ulcer),
- swelling of the breast tissue in males (gynaecomastia),
- increased blood sugar levels (hyperglycaemia), or decrease in blood sugar levels (hypoglycaemia) which could include symptoms such as thirst, increased urination, blurred vision, confusion, anxiety and shakiness,
- difficulty in breathing, asthma, tightness in the chest.

Side effects with unknown frequency (frequency cannot be estimated from available data):

- a condition in which high levels of a hormone cause the body to retain water, called syndrome of inappropriate antidiuretic hormone secretion (SIADH),
- infection of salivary glands (sialadenitis) with symptoms such as pain, tenderness, redness and swelling in the affected area,
- yellow vision (xanthopsia),
- muscle spasms,
- if your doctor confirms the presence of glucose in the urine (glycosuria) after a urine test,
- a condition in which some areas of the body feel numb and cool in certain circumstances due to smaller blood vessels that supply blood to the skin constricting excessively in response to cold (Raynaud's phenomenon),
- decrease in vision or pain in your eyes due to high pressure (possible signs of fluid accumulation in the vascular layer of the eye (choroidal effusion) or acute angle-closure glaucoma).

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 side effects to:

SAHPRA: via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

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

5. How to store PHARMAPRESS CO

Store all medicines out of reach of children.

Store at or below 25 °C.

Protect from light.

Store in a dry place.

Keep in original packaging until required for use.

Do not store in bathrooms.

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

Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

What PHARMAPRESS CO contains

The active substances are 20 mg of enalapril maleate and 12,5 mg hydrochlorothiazide.

The other ingredients are lactose monohydrate, maize starch, zinc stearate.

What PHARMAPRESS CO looks like and contents of the pack

A round, white to off-white biconvex tablet.

28 or 30 tablets are packed in a matt silver polyamide, aluminium and polyvinylchloride film sealed with an aluminium foil backing. The blister strip is packed into an outer cardboard carton.

Holder of Certificate of Registration

PHARMACARE LIMITED

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