1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

PHARMAPRESS 10 mg tablets

Enalapril maleate

Contains sugar: Lactose monohydrate 66,435 mg

PHARMAPRESS 20 mg tablets

Enalapril maleate

Contains sugar: Lactose monohydrate 133,246 mg

Read all of this leaflet carefully before you start taking PHARMAPRESS

- 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.
- PHARMAPRESS 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 PHARMAPRESS is and what it is used for

PHARMAPRESS belongs to a group of medicines called Angiotensin-converting enzyme inhibitors (ACE inhibitors). It works by causing blood vessels to relax, lowering blood pressure, and increasing the supply of blood and oxygen to the heart.

PHARMAPRESS is used in adults to:

- treat high blood pressure (hypertension) including renovascular hypertension (caused by high blood pressure due to narrowing of the arteries that carry blood to the kidneys).
- the treatment of heart failure (weakening of the heart function), usually combined with other medicines used for high blood pressure (diuretics) and medicine used to treat heart rhythm problems (digoxin).
- the treatment of a form of heart failure with no symptoms (asymptomatic left ventricular dysfunction). PHARMAPRESS decreases the rate of development of heart failure with symptoms and decreases the incidence of hospitalisation for heart failure.

2. What you need to know before you take PHARMAPRESS

Do not take PHARMAPRESS:

- if you are hypersensitive (allergic) to enalapril maleate, to any other medicine belonging to the same group (ACE inhibitors) or any of the other ingredients of PHARMAPRESS (listed in section 6).
- if you ever had swelling of the face, mouth, throat, lips, eyes, or tongue which caused difficulty in swallowing or breathing (angioedema or hereditary or idiopathic angioedema) related to taking ACE-inhibitor therapy or angiotensin receptor blockers (ARBs) before or due to an unknown cause. **You should never receive PHARMAPRESS again.**
- if you have heart problems which cause narrowing of the vessels in the heart (aortic stenosis).
- if you have heart problems which cause hardening of the heart muscles (hypertrophic

obstructive cardiomyopathy).

- if you have severe kidney problems.
- if you have high blood pressure caused by the kidney and you have only one kidney (renal artery stenosis).
- if you have a condition where the arteries from both your kidneys are narrowed resulting in increased blood pressure (bilateral renal artery stenosis).
- if you are taking medicines to treat high blood pressure such as spironolactone, triamterene, amiloride (potassium-sparing diuretics).
- 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 together with a fluoroquinolone antibiotic.
- if you are taking lithium, which is used to treat mental illnesses.
- if you have porphyria.
- if you have diabetes or kidney problems and you are taking a medicine containing aliskiren, used to lower blood pressure.
- if you are taking medicine containing sacubitril and valsartan used to treat heart failure.
- if you are pregnant or breastfeeding your baby.

Warnings and precautions

Take special care with PHARMAPRESS:

If you become pregnant while taking PHARMAPRESS, you must talk to your doctor immediately so that treatment with PHARMAPRESS may be stopped. Your doctor will prescribe a different medicine that may be used in pregnancy. If you are planning to become pregnant, you must tell your doctor so that they can prescribe a different medicine.

PHARMAPRESS is not recommended during breastfeeding (see Pregnancy, breastfeeding, and fertility).

- If you have ever had an allergic reaction, ‘angioedema’. The signs include itching, red marks on the hands, feet, and throat, swelling of the face, around the eyes, lips, tongue, or throat with difficulty in swallowing or breathing,
- if your ethnicity is black, as you may have a higher risk of developing side effects, PHARMAPRESS may also be less effective in lowering your blood pressure than in the non-black population,
- if you are undergoing treatment to reduce your response to bee or wasp stings (hymenoptera venom desensitisation). You may have to stop PHARMAPRESS while undergoing this treatment,
- if you are taking a medication called dextran sulfate to lower your cholesterol,
- if you have low blood pressure (you may notice this as fainting or dizziness, especially when standing up),
- if you are on a diet that restricts your salt intake or if you have low levels of sodium in your blood (hyponatraemia),
- if you have experienced excessive vomiting or diarrhoea recently or if you are dehydrated,
- if you are receiving dialysis,
- if you have an obstruction of blood flow across the aortic or mitral valve in the heart,
- if you have any type of kidney. You may need a lower dose of PHARMAPRESS and may be at risk of developing high levels of potassium in your blood or low blood pressure,
- if you have had a kidney transplant,
- if you have liver problems,
- if you have low levels of white blood cells (neutropenia/agranulocytosis), a low platelet count (thrombocytopenia) or fewer red blood cells (anaemia). Symptoms may include

increased susceptibility to infections, fever, tiredness, excessive bruising, prolonged bleeding, shortness of breath, light-headedness, dizziness, or a fast heartbeat,

- if you are taking antibiotics called fluoroquinolones as these could cause damage to the kidneys,
- if you have a problem with blood flow to the heart (ischaemic heart disease) or brain (ischaemic cerebrovascular disease) the narrowing of arteries by plaque,
- if you have diabetes and you are using medicine to control your blood sugar. You should monitor your blood for low blood sugar levels, especially during the first month of treatment. The level of potassium in your blood can also be higher (hyperkalaemia),
- if you are going to undergo major surgery or if you are going to receive anaesthesia,
- if you develop a persistent cough without phlegm after starting PHARMAPRESS,
- if you are taking medicines such as racecadotril (medicine used in the treatment of diarrhoea), sirolimus, everolimus, temsirolimus (used in the treatment of some cancers) or vildagliptin (used in the treatment of diabetes) as these may cause angioedema.

The safe use of PHARMAPRESS in children has not been established.

Other medicines and PHARMAPRESS

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:

- Fluoroquinolones (e.g. ciprofloxacin, ofloxacin, moxifloxacin, levofloxacin): medicines used to treat specific bacterial infections.
- Antihypertensive medicines such vasodilators (e.g. nitroglycerine, nitrates), aliskiren, sacubitril/valsartan, angiotensin II receptor blockers (ARBs) (e.g. losartan, valsartan, telmisartan), diuretics (e.g. hydrochlorothiazide, furosemide, spironolactone, triamterene, eplerenone, amiloride), calcium channel blockers (e.g. amlodipine diltiazem), beta blockers (e.g. propranolol), methyldopa, ganglionic blocking medicines (e.g

hexamethonium): medicines used to treat high blood pressure and sometimes heart failure.

- Non-steroidal anti-inflammatory drugs (NSAIDs) and COX-2 inhibitors (e.g. indomethacin, ibuprofen, diclofenac, celecoxib, aspirin): medicine used to treat pain, swelling and inflammation.
- Thrombolytics (e.g. streptokinase): medicine used to dissolve blood clots.
- Potassium supplements (e.g. potassium chloride): medicine used to supplement the amount of potassium in the body.
- Salt substitutes that contain potassium.
- Immunosuppressant medicines (e.g. ciclosporin, temsirolimus, sirolimus, everolimus): medicines used to treat certain types of cancer or to prevent the body's immune system for rejecting a transplanted organ.
- Anticoagulants (e.g. heparin): medicine used to thin the blood to treat and prevent blood clots from forming in the body.
- Lithium: medicine used to treat mental illnesses.
- Antidepressants (e.g. amitriptyline): medicine used to treat depression.
- Racecadotril: medicine used to treat diarrhoea.
- Gold (e.g. sodium aurothiomalate): medicine used to treat rheumatoid arthritis.
- Sympathomimetic medicines: medicines used in certain cough and cold medicines or weight loss medicines.
- Antidiabetic medicines (e.g. insulin, vildagliptin, metformin): medicine used to treat high blood sugar in diabetic patients.
- Anaesthetics: medicine used during surgery to induce sleep.
- Antipsychotics: medicine used to treat mental illnesses such as schizophrenia.
- Allopurinol: medicine used to treat gout.
- Procainamide: medicine used to treat heart rhythm problems.
- Narcotics (e.g.codeine): medicines used for pain relief.

PHARMAPRESS with food and drink

PHARMAPRESS may be taken with or without food, preferably at the same time each day.

Avoid drinking alcohol as the use of alcohol may cause low blood pressure.

Pregnancy, breastfeeding, and fertility

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

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 this medicine.

If you become pregnant while taking PHARMAPRESS, you must contact your doctor immediately. Your doctor will stop PHARMAPRESS immediately and change you to a different medicine which is safe to use during pregnancy.

Babies who have been exposed to PHARMAPRESS while their mother was pregnant, will be closely monitored by a doctor.

Driving and using machines

PHARMAPRESS has a minor influence on the ability to drive and use machines.

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

PHARMAPRESS contains lactose monohydrate

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

3. How to take PHARMAPRESS

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

Always take PHARMAPRESS exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is:

High blood pressure

The initial dose in adults is 10 mg to 20 mg once daily. The dose should be adjusted according to your blood pressure response. The usual effective maintenance dose is 20 mg per day given as a single dose.

High blood pressure caused by the kidneys (renovascular hypertension)

The usual starting dose of PHARMAPRESS is 5 mg or less. Your doctor will adjust your dose depending on your body's response. The usual maintenance dose is 20 mg of PHARMPRESS a day.

Use during diuretic therapy

The initial dose is 5 mg or less as you may experience hypotension. Your doctor will adjust the dose according to your body's response.

Renal impairment

The initial dose can range between 5 mg and 2,5 mg depending on your condition.

Heart failure

The initial dose of PHARMAPRESS is 2,5 mg. Your doctor will monitor your blood pressure to determine how PHARMAPRESS affects you.

The dose may be increased gradually to the usual maintenance dose of 20 mg, given in a single dose or in two divided doses.

Your blood pressure, kidney function and potassium levels will be monitored closely before and after starting treatment with PHARMAPRESS.

If you are being treated with diuretics, your dose of diuretics may be lowered or even stopped if possible before beginning treatment with PHARMAPRESS.

If you experience low blood pressure after starting PHARMAPRESS, this does not mean that the low blood pressure will continue happening throughout your treatment with PHARMAPRESS.

If you have kidney problems your doctor will start you on a very low dose and gradually increase the dose if necessary, according to your body's response.

Your doctor will tell you how long your treatment with PHARMAPRESS will last. Do not stop treatment early because your condition may worsen. If you have the impression that the effect of PHARMAPRESS is too strong or too weak, tell your doctor or pharmacist.

If you take more PHARMAPRESS 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. Overdosage with PHARMAPRESS can cause low blood pressure, heart palpitations, dizziness, and anxiety.

If you forget to take PHARMAPRESS

Take your missed dose as soon as you remember, if within a few hours after missing a dose. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

PHARMAPRESS can have side effects.

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

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

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting,
- blistering of the skin, mouth, eyes, and genitals as these may be due to a serious allergic reaction known as Stevens-Johnson Syndrome (SJS) and detachment of the skin known as Toxic epidermal necrolysis (TEN).

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

- Severe decrease in a particular type of white blood cells which makes infections more likely (neutropenia/agranulocytosis),
- reduction in blood platelets, which increases risk of bleeding or bruising (thrombocytopenia),

- reduction in volume of the red cells in the blood (haemoglobin and haematocrit), decreased number of red blood cells which can make the skin pale and cause weakness or breathlessness (anaemia, haemolytic anaemia),
- total depression of all blood cells made in the bone marrow (bone marrow depression, pancytopenia),
- fever, inflammation of membranes, muscles, joints and blood vessels, muscle pain and joint pain and an increased number of a certain types of white blood cells in the blood (eosinophilia, leucocytosis). You may experience all these symptoms together,
- too much potassium in the blood which can cause abnormal heart rhythm (hyperkalaemia),
- sudden, painful squeezing sensation in your chest, heart rhythm disturbances, fast or irregular heartbeat, anxiety and light-headedness which are signs of a heart attack (myocardial infarction),
- numbness of the face, arm or leg, trouble walking, speaking, and understanding which are signs of a stroke (cerebrovascular accident),
- inflammation of the lungs, fluid in the lungs with symptoms such as shortness of breath, cough that produces phlegm or sometimes blood and chest or muscle pain (allergic alveolitis/eosinophilia pneumonia),
- inflammation of the pancreas (pancreatitis) which causes nausea and severe pain in the stomach and back,
- liver problems such as inflammation of the liver (hepatitis), blockage of flow of bile from the liver with symptoms such as yellowing of the skin or whites of the eyes (jaundice), nausea, stomach pain and fever,
- kidney problems/failure with symptoms such as swelling, extreme tiredness and confusion (renal failure),
- loss of consciousness for a short period of time due to sudden change in blood flow to the brain (syncope),

- blistering of the skin and the inside of the mouth, nose, throat, eyes, and genitals (pemphigus),
- squeezing, pressure, heaviness, tightness, or pain in the chest (angina pectoris),
- lesions on the skin (erythema multiforme), redness and peeling of the skin (exfoliative dermatitis),
- lack of movement in the intestines that can lead to pain, nausea and bloating due to a build-up of waste (ileus),
- swelling of the intestines resulting in stomach pains (intestinal angioedema).

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:

- Persistent feeling of sadness and loss of interest (depression),
- dizziness, headache, taste distortion,
- blurred vision,
- fast heartbeat (tachycardia), change in the way your heart beats (rhythm disturbance),
- low blood pressure or a fall in blood pressure on standing up which causes dizziness, light-headedness, or fainting (orthostatic hypotension),
- cough, difficulty breathing (dyspnoea),
- loose stools (diarrhoea), feeling sick (nausea), stomach pain,
- feeling very tired (fatigue), abnormal physical weakness, or lack of energy (asthenia),
- change in blood results showing how your kidneys are working.

Less frequent side effects:

- Swelling of the immune system glands due to an infection (lymphadenopathy),
- disease in which the body's immune system attacks healthy cells (autoimmune diseases),
- low blood levels of sodium which can cause tiredness, confusion, muscle twitching, fits

and coma (hyponatraemia), low blood sugar levels (hypoglycaemia), decreased weight which may be cause anorexia,

- confusion, sleep disorders, extreme sleepiness, nervousness, sleeplessness (insomnia), dream abnormality,
- numbness or tingling pressure of the skin (paraesthesia), spinning sensation (vertigo),
- ringing in the ears (tinnitus),
- feeling that your heart is pounding or racing (palpitations),
- flushing, discolouration of the fingers and/or toes due to an abnormal spasm of the blood vessel after exposure to changes in temperature (hot or cold) or emotional events (Raynaud's phenomenon),
- asthma, tightening of chest muscles (bronchospasm), swelling and irritation inside the nose (rhinitis), runny nose (rhinorrhoea), sore throat and change in pitch or quality of voice (hoarseness),
- presence of some unusual substance in the lungs (pulmonary infiltrates),
- bloating while or after eating (dyspepsia), dry mouth, vomiting (being sick), constipation, stomach irritations, ulcers on the inside lining of your stomach and the upper portion of your small intestine (peptic ulcers), inflammation of the tongue (glossitis), inflammation and shallow sores inside the mouth or at the base of the gums (stomatitis),
- hives (urticaria), increased sweating (diaphoresis), hair loss (alopecia), widespread reddening and inflammation of the skin (erythroderma),
- muscle cramps,
- decreased urine output (oliguria),
- high level of protein in your urine (proteinuria),
- loss of male sexual ability (impotence), enlargement of male breast tissue (gynaecomastia),
- fever, a general feeling of discomfort or illness (malaise),

- increase of urea (a waste product that your kidneys remove from your blood), bilirubin and liver enzymes in blood results.

Side effects with an unknown frequency:

- A condition in which high levels of hormone cause the body to retain water known as syndrome of inappropriate antidiuretic hormone secretion (SIADH),
- sensitivity of the skin to light (photosensitivity).

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/<+27 (0)11 239-6200

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

5. How to store PHARMAPRESS

Store all medicines out of reach of children.

Store at or below 25 °C.

Protect from moisture.

Keep the blisters in the carton until required for use.

Do not store in a bathroom.

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 contains

PHARMAPRESS 10 mg

The active substance is 10 mg of enalapril maleate.

The other ingredients are FD&C blue/indigo carmine lake (C.I. 73015), FD&C yellow/sunset yellow FCF lake (C.I. 15985), ponceau 4R lake (C.I. 16255), starch maize, zinc stearate.

Contains sugar: lactose monohydrate.

PHARMAPRESS 20 mg

The active substance is 20 mg of enalapril maleate.

Alumina, indigo carmine lake (C.I. 73015), sodium chloride, sodium sulphate, starch maize, sunset yellow FCF lake (C.I. 15985), zinc stearate.

Contains sugar: lactose monohydrate.

What PHARMAPRESS looks like and contents of the pack

PHARMAPRESS 10 mg

PHARMAPRESS 10 mg is a round, pink tablet with bevelled edges, bisected on one side.

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

PHARMAPRESS 20 mg

PHARMAPRESS 20 mg is a round, peach tablet with bevelled edges, bisected on one side.

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

Not all packs and pack sizes are necessarily marketed.

Holder of Certificate of Registration

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Registration number

PHARMAPRESS 10 mg	33/7.1.3/0479
PHARMAPRESS 20 mg	33/7.1.3/0480

Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and

Patient Information Leaflets:

https://www.sahpra.org.za/pi-pil-repository/

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

Namibia:	NS2
PHARMAPRESS 10 mg:	04/7.1.3/0112
PHARMAPRESS 20 mg:	04/7.1.3/0121

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