PATIENT INFORMATION LEAFLET (APPROVED)

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S3

PEARINDA PLUS 8, tablets

Perindopril and Indapamide

PEARINDA PLUS 8 contains sugar (lactose 123,060 mg per tablet)

Read all of this leaflet carefully before you start taking PEARINDA PLUS 8

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist, nurse, or other healthcare provider.
- PEARINDA PLUS 8 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

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1. What PEARINDA PLUS 8 is and what it is used for

Perindopril belongs to a class of medicines called ACE inhibitors (angiotensin converting enzyme inhibitors). It works by blocking ACE, an enzyme involved in narrowing blood vessels and causing sodium and fluid retention by the kidneys. This causes blood vessels to relax, allowing blood to flow more freely and at a lower pressure, and increasing the heart's ability to pump blood in some types of heart failure.

Indapamide is a diuretic (sometimes called a water tablet). Diuretics work by making the kidneys pass more urine out of the body.

PEARINDA PLUS 8 is a combination of two active substances, perindopril tert-butylamine and indapamide. It is used to treat high blood pressure (hypertension).

PEARINDA PLUS 8 is prescribed for patients where blood pressure is not adequately controlled by taking either perindopril or indapamide tablets.

2. What you need to know before you take PEARINDA PLUS 8

Do not take PEARINDA PLUS 8:

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- if you are hypersensitive (allergic) to perindopril tert-butylamine, or any other ACE inhibitor, or to indapamide or any other sulphonamide, or any of the other ingredients of PEARINDA PLUS 8 (see section 6)
- if you have had symptoms such as swelling of the face, tongue or throat, wheezing, skin rashes, intense itching, dizziness or fainting with previous ACE inhibitor or angiotensin receptor blocker (ARB) or renin inhibitor treatment (you should never take these medicines again) or have had these symptoms in any other circumstances (a condition called angioedema) or if you or a member of your family have had these symptoms in any other circumstances
- contact your doctor to re-evaluate your treatment if you are treated with ACE inhibitors/angiotensin receptor blockers together with a fluoroquinolone antibiotic such as ciprofloxacin, gemifloxacin, levofloxacin, moxifloxacin and norfloxacin
- if you have narrowing of the main blood vessel leading from the heart (aortic stenosis), mitral valve stenosis or heart muscle disease (hypertrophic cardiomyopathy) or narrowing of the artery supplying the kidney with blood (renal artery stenosis)
- if you have severe kidney disorder or if you are receiving dialysis
- if you are taking potassium supplements, potassium-containing salt substitutes or potassium-sparing diuretics (water tablets) such as spironolactone, triamterene and amiloride
- if you have porphyria (a rare blood disorder)
- if you are taking lithium (to treat mood disorders)

- if you are taking aliskiren (a renin inhibitor that decreases blood pressure)
- if you have a problem with your adrenal glands called Addison's disease
- if you suffer from heart failure which is not well controlled, or are taking any medicines which may cause an abnormal heart rhythm
- if you are being treated with sacubitril/valsartan (used to treat heart failure)
- if you have a severe liver disorder, or suffer from a condition called hepatic encephalopathy (degenerative disease of the brain)
- if you have low blood potassium levels
- if you are on dialysis
- if you are undergoing blood transfusions
- if you are pregnant or breastfeeding (see Pregnancy, breastfeeding, and fertility).

Warnings and precautions

Take special care / Special care should be taken with PEARINDA PLUS 8:

- if you suffer from a collagen disease (skin disease) such as systemic lupus erythematosus or scleroderma
- if you are of black origin, you may have a higher risk of angioedema (swelling of the lower layer of skin and tissue) and PEARINDA PLUS 8 may be less effective in lowering your blood pressure than in non-black patients
- if you are undergoing dialysis, an allergic reaction may occur if you are taking PEARINDA PLUS 8

- if you had a kidney transplant or you are undergoing dialysis, you may become anaemic (below normal red blood cell count)
- if you have severe liver disease or liver failure
- if you have kidney disease, or have been diagnosed with renal artery stenosis (narrowing of one of the renal arteries)
- if you become dehydrated (volume depleted), e.g., if you were vomiting, or had diarrhoea or heavy sweating
- if you have heart problems or heart failure
- if you have diabetes that is not well controlled, or are insulin dependent
- if you have problems that affect blood supply to your brain (cerebrovascular disease such as atherosclerosis) or a condition that affects the supply of blood to the heart (ischaemic heart disease)
- if you suffer from hyperparathyroidism (an overactive parathyroid gland)
- if you suffer from gout
- if you have an eye condition where the pressure inside your eye rises causing severe eye pain, headache, nausea/vomiting, seeing halos around lights.

Your doctor may check your kidney function, blood pressure and the amounts of electrolytes (e.g., potassium, sodium, and calcium in your blood) at regular intervals.

You should inform your doctor, pharmacist, or healthcare provider before you take PEARINDA PLUS 8:

- if you think you are pregnant or might become pregnant as PEARINDA PLUS 8 must not be taken in pregnancy as it may cause serious harm to your baby. (see Pregnancy, breastfeeding, and fertility)
- if you are going to have an operation or anaesthesia
- if you are to undergo a procedure to remove cholesterol from your blood by a machine (LDL apheresis)
- if you are going to have desensitisation treatment to reduce the effects of an allergy to bee or wasp stings
- if you experience any signs of infection such as sore throat, fever, and chills (signs of neutropenia or agranulocytosis, where the bone marrow does not produce enough white blood cells that help fight infection)
- if you experience bleeding from your gums or nose, blood in your urine or stool, or bruise easily (thrombocytopenia, which results in problems with blood clotting)
- if you look pale, feel tired or dizzy and have a shortness of breath due to anaemia (a reduction of red blood cells or haemoglobin in the blood)
- if you develop a dry cough while taking PEARINDA PLUS 8 as this medicine is associated with a dry persistent cough
- if you experience a high sensitivity to sunlight (photosensitivity)
- if you are an athlete, as the use of PEARINDA PLUS 8, may result in a positive doping test

- if you have been told by a doctor that you have low sodium, magnesium or potassium levels in your blood, or high calcium levels in your blood.

Children and adolescents

PEARINDA PLUS 8 should not be given to children and adolescents.

Other medicines and PEARINDA PLUS 8

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

You should not take PEARINDA PLUS 8 with any of the following:

- fluoroquinolone antibiotics (when taken with PEARINDA PLUS 8 may cause kidney problems)
- lithium (for mania and depression)
- potassium supplements, potassium-containing salt substitutes and potassium-sparing diuretics (water tablets) such as spironolactone, triamterene or amiloride
- aliskiren (a direct renin inhibitor) may result in low blood pressure, low blood potassium levels and reduced kidney function when used with PEARINDA PLUS 8
- sacubitril/valsartan (used to treat heart failure).

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

- other medicines for treating high blood pressure called angiotensin receptor blockers, e.g., valsartan, telmisartan may decrease your blood pressure further when taken with PEARINDA PLUS 8
- estramustine (used in the treatment of prostate cancer) may increase the risk of angioedema (swelling of the lower layer of skin and tissue)
- baclofen (to treat muscle stiffness occurring in diseases such as multiple sclerosis) may cause blood pressure to fall lower than normal
- nonsteroidal anti-inflammatory medicines (NSAIDs), including aspirin, ibuprofen in high doses, and indomethacin decrease the antihypertensive effects of PEARINDA PLUS 8
- medicines to treat diabetes such as insulin, metformin, or gliptins (linagliptin, saxagliptin, sitagliptin, vildagliptin) may further lower blood sugar levels if used with PEARINDA PLUS 8
- medicines that may cause heart rhythm problems when your blood potassium levels are low such as procainamide, sotalol, digoxin, quinidine, hydroquinidine, disopyramide, amiodarone, dofetilide, ibutilide, bretylium
- some neuroleptics (used to treat mental illnesses) such as chlorpromazine, cyamemazine, levomepromazine, thioridazine, trifluoperazine, pimozide, amisulpride, sulpiride, tiapride, droperidol and haloperidol may cause irregular heartbeats if low blood potassium levels are present

- medicines such as, bepridil (to treat angina), cisapride (to treat gastric reflux), diphemanil (to treat excessive sweating), intravenous erythromycin (an antibiotic), halofantrine (for certain types of malaria) and pentamidine (for treatment of some types of pneumonia), mizolastine, terfenadine, astemizole (used in the treatment of hay fever), moxifloxacin (an antibiotic) and methadone (used in the prevention of withdrawal symptoms) may cause irregular heartbeats if you have low blood potassium
- medicines that reduce blood potassium levels including stimulant laxatives such as senna and amphotericin B (for fungal diseases) may reduce your blood potassium levels
- digoxin (for the treatment of heart problems) may have harmful effects if your blood potassium or magnesium levels are low
- allopurinol (to treat gout)
- immunosuppressants used to treat auto-immune disorders or following transplant surgery to prevent rejection (e.g., ciclosporin)
- ciclosporin (immunosuppressant medicine used in treatment of rheumatoid arthritis, psoriasis, Crohn’s disease, nephrotic syndrome and to prevent organ transplant rejection) may cause increased creatinine levels which may indicate possible kidney problems
- medicines used to treat mental illnesses such as depression, anxiety, schizophrenia (tricyclic antidepressants, neuroleptics), e.g., imipramine, may lower your blood pressure further when taken with PEARINDA PLUS 8

- corticosteroids, such as prednisone used to treat various conditions including severe asthma and rheumatoid arthritis, tetracosactide (to treat Crohn's disease) may decrease the effects of PEARINDA PLUS 8 and may reduce your potassium levels
- other blood pressure lowering medicines, including nitroglycerin, other nitrates, e.g., isosorbide dinitrate and loop or thiazide diuretics (water tablets), e.g., hydrochlorothiazide, may increase the antihypertensive effects of PEARINDA PLUS 8
- if you are going to have an operation or anaesthesia as the effect of the anaesthetic may be increased
- gold salts, especially given intravenously, e.g., auranofin, to treat rheumatoid arthritis, may cause facial flushing, nausea, vomiting and low blood pressure if used with PEARINDA PLUS 8
- if you are to undergo a medical test that requires injection of a substance that makes organs like the kidney or stomach visible on an x-ray (iodinated contrast agent)
- calcium salts taken with PEARINDA PLUS 8 can cause increased blood levels of calcium as less calcium is eliminated from the body in the urine
- co-trimoxazole (an antibiotic for infections) may cause a higher than normal potassium level in your blood with symptoms such as palpitations, muscle pain, muscle weakness or numbness
- racecadotril (for treating diarrhoea) and sirolimus, everolimus, temsirolimus (cancer treatments) can cause severe swelling under the skin commonly affecting the hands, feet, eyes, cheeks, and lips.

PEARINDA PLUS 8 with food and drink

It is recommended that PEARINDA PLUS 8 should be taken once daily before a meal.

Pregnancy, breastfeeding, and fertility

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 using PEARINDA PLUS 8.

You should not take PEARINDA PLUS 8 if you are pregnant or breastfeeding your baby (see Do not take PEARINDA PLUS 8).

Driving and using machines

You may experience dizziness, light-headedness or eyesight problems while taking PEARINDA PLUS 8.

It is not always possible to predict to what extent PEARINDA PLUS 8 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 PEARINDA PLUS 8 affects them.

PEARINDA PLUS 8 contains lactose

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

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3. How to take PEARINDA PLUS 8

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

Always take PEARINDA PLUS 8 exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Adults:

The usual dose of PEARINDA PLUS 8 is one tablet taken once daily in the morning before a meal.

Swallow the tablet with a glass of water, preferably at the same time each day.

Your doctor will tell you how long your treatment with PEARINDA PLUS 8 will last. Do not stop treatment early because your high blood pressure may return.

If you have the impression that the effect of PEARINDA PLUS 8 is too strong or too weak, tell your doctor or pharmacist.

If you take more PEARINDA PLUS 8 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.

Symptoms of overdose may include:

- low blood pressure. If marked low blood pressure occurs, symptoms such as dizziness or faintness, nausea, vomiting, cramps, mental confusion, and reduced urine output and electrolyte imbalances may occur.
- Other symptoms associated with overdosage of ACE inhibitors may include circulatory shock (a life-threatening condition in which blood flow to body tissues is inadequate and cells are deprived of oxygen), electrolyte disturbances, kidney failure, hyperventilation, irregular heartbeat, dizziness, anxiety, and cough.

If you forget to take PEARINDA PLUS 8

If you forget to take PEARINDA PLUS 8, take a dose as soon as you remember, take your normal dose the next day. Do not take a double dose to make up for forgotten individual doses.

If you stop taking PEARINDA PLUS 8

As the treatment for high blood pressure is usually life-long, you should discuss with your doctor before stopping PEARINDA PLUS 8.

4. Possible side effects

PEARINDA PLUS 8 can have side effects.

Not all side effects reported for PEARINDA PLUS 8 are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while using PEARINDA PLUS 8, please consult your doctor, pharmacist, or other healthcare professional for advice.

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If any of the following happens, stop using PEARINDA PLUS 8 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
- severe dizziness or fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to PEARINDA PLUS 8. 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:

- tightening of the chest, wheezing and shortness of breath, irregular heartbeat, chest pain, uncomfortable pressure, squeezing, fullness or pain in the center of your chest (heart attack)
- unusually fast or irregular heartbeat
- drooping face, arm weakness and slurred speech (stroke)
- kidney problems include passing less than normal urine or no urine, swelling, fatigue and shortness of breath, which could be symptoms of acute renal failure
- jaundice (yellowing of the skin and eyes)

- hepatitis (inflammation of the liver with symptoms such as nausea, mild fever, abdominal pain), abnormal liver function (clay coloured stool, dark urine, itching, loss of appetite), hepatic encephalopathy (forgetfulness, confusion and breath with a sweet or musty odour)
- Toxic epidermal necrolysis (TEN) (a life-threatening skin disorder with symptoms such as a painful red area that spreads quickly, skin peeling without blisters, raw areas of skin) or Stevens-Johnson syndrome or other serious skin disorder (begins with flu-like symptoms, followed by a painful red or purplish rash that spreads and blisters)
- severe body fluid loss/dehydration
- pancreatitis (inflammation of the pancreas with symptoms such as stomach pain, increased heart rate and fever).

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:

- weakness, cramping in arm or leg muscles, tingling or numbness (low potassium levels)
- headache, decreased appetite, dizziness, spinning feeling, pins and needles, burning/numb/chilly feeling on the skin
- eyesight changes
- ringing sound in ears

- low blood pressure when standing up from a sitting or lying down position, low blood pressure
- dry cough
- diarrhoea, nausea, indigestion, vomiting, taste disturbances, dry mouth, constipation, severe stomach pain, anorexia (abnormally low body weight due to a decrease in food consumed)
- severe itching of the skin (pruritus), red rash on the skin that is covered with small bumps, skin rash
- muscle cramps.

Less frequent side effects:

- anaemia (reduced number of red blood cells with symptoms such as feeling generally tired or lethargic, pale skin), decrease in blood platelets which may result in unusual bruising or easy bleeding (red blood cell damage), weakness, bruising and frequent infections (aplastic anaemia), signs of infection such as sore throat, fever, and chills (low white blood cell count)
- gout (high levels of uric acid in the blood), liver inflammation or damage, blood glucose test results showing increased or decreased blood sugar levels

- symptoms of electrolyte imbalance in the blood:
    - high levels of potassium (heart palpitations, shortness of breath, or chest pain)
    - low levels of sodium (headache, confusion and fatigue)
    - low levels of chloride (confusion, hand tremor, muscle twitching, numbness or tingling in the face, hands, or feet)
    - high levels of calcium (increased thirst and urination, stomach pain, nausea, bone pain, muscle weakness, confusion and fatigue)
- high levels of creatine in the blood (fatigue, loss of appetite, bad taste in your mouth, muscle twitching)
- a condition in which the liquid portion of the blood is too low (hypovolaemia) which can cause weakness, fatigue, fainting and dizziness.
- blood tests can show increased levels of urea, increase in liver enzymes, decrease in haemoglobin and decrease in the volume percentage of red blood cells in blood
- mood changes, sleep disturbances, mental confusion
- blocked nose, sore throat and discomfort when swallowing, viral infections, chest infection, sinusitis, sneezing/runny nose caused by inflammation of the lining of the nostrils (rhinitis), inflammation in the lungs, excess fluid in the lungs
- alopecia (spot baldness), psoriasis (chronic skin condition that causes itchy or sore patches of thick red skin with silvery scales, sensitivity to light, urticaria, purpura (red pinpoints on skin), vasculitis (inflammation of the blood vessels), flushing, excessive sweating

- severe skin disease that causes rash, red skin, blistering of the lips, eyes or mouth, skin peeling, fever (erythema multiforme), facial rash, joint pain, muscle disorder, fever (lupus erythematosus), rash of round, red welts on the skin that itch intensely, sometimes with dangerous swelling
- abnormal physical weakness or lack of energy
- sweating, general feeling of discomfort, illness, or unease, swelling of your lower legs or hands, fever, fatigue
- muscle aches and pain
- impotence, unable to maintain an erection.

The following side effects have been reported but the frequency for them to occur is not known:

- short sighted, blurred vision
- abnormal electrocardiogram (EGC) reading
- tendency to fall
- large, fluid-filled blisters on the skin
- drowsiness
- symptoms of electrolyte imbalance in the blood:
    - low levels of potassium (abnormal heart rhythm, fatigue and muscle problems)
    - low levels of magnesium (nausea, vomiting, lethargy, weakness, tremor, and muscle problems).

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 online service for adverse drug reaction reporting by following the links: https://www.sahpra.org.za/document/adverse-drug-reactions-and-quality-problem-reporting-form/ or https://www.sahpra.org.za/Publications/Index/8

By reporting side effects, you can help provide more information on the safety of PEARINDA PLUS 8. You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za, to ensure safety of the product.

5. How to store PEARINDA PLUS 8

Store all medicines out of reach of children.

Store at or below 30˚C in a cool, dry place.

Keep tablets in the blister until required for use.

Keep 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).

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6. Contents of the pack and other information

What PEARINDA PLUS 8 contains

The active substances are Perindopril *tert*-butylamine and Indapamide.

Each tablet contains 8 mg perindopril *tert*-butylamine and 2,5 mg indapamide.

The other ingredients are

Tablet cores:

Lactose monohydrate, magnesium stearate, microcrystalline cellulose,

silica colloidal anhydrous.

What PEARINDA PLUS 8 looks like and contents of the pack

White to almost white, circular tablets, bearing a break-line on one side.

PEARINDA PLUS 8 tablets are available in in silver polyamide, aluminium, and PVC blisters.

The tablets are packed as 30 tablets into a cardboard box.

Holder of Certificate of Registration

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