

# PATIENT INFORMATION LEAFLET

## PEARINDA PLUS 4

### SCHEDULING STATUS

S3

### PEARINDA PLUS 4 tablets

### Perindopril *tert*-butylamine salt and indapamide

**PEARINDA PLUS 4: Contains sugar (lactose monohydrate 61,53 mg per tablet).**

### Read all of this leaflet carefully before you start taking PEARINDA PLUS 4

- 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.
- PEARINDA PLUS 4 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 PEARINDA PLUS 4 is and what it is used for
2. What you need to know before you take/use PEARINDA PLUS 4
3. How to take/use PEARINDA PLUS 4
4. Possible side effects
5. How to store PEARINDA PLUS 4
6. Contents of the pack and other information

#### 1. What PEARINDA PLUS 4 is and what it is used for

PEARINDA PLUS 4 is a combination of two active ingredients, i.e. perindopril and indapamide.

Perindopril belongs to a class of medicines called ACE inhibitors. These work by widening the blood vessels, which makes it easier for your heart to pump blood through them.

## PATIENT INFORMATION LEAFLET

### PEARINDA PLUS 4

Indapamide is a diuretic (sometimes called a water tablet). Diuretics increase the amount of urine produced by the kidneys. However, indapamide is different from other diuretics, as it only causes a slight increase in the amount of urine produced.

PEARINDA PLUS 4 is used to treat high blood pressure (hypertension).

#### **2. What you need to know before you take/use PEARINDA PLUS 4**

##### **Do not take PEARINDA PLUS 4:**

- if you are hypersensitive (allergic) to perindopril or any other ACE inhibitor, or to indapamide or any other sulphonamides, or to any of the ingredients of PEARINDA PLUS 4 (see section 6)
- if you have ever had symptoms such as swelling of the face, tongue or throat, wheezing, skin rashes, intense itching, dizziness or fainting with previous ACE inhibitor and/or angiotensin receptor blockers (ARBs) treatment or have had these symptoms in any other circumstances (this is a condition called angioedema); these patients should never again be given these medicines
- if you have hereditary or idiopathic angioedema
- if you have narrowing of the main blood vessel leading from the heart or heart muscle disease or narrowing of the artery supplying the kidney with blood
- if you are treated with ACE inhibitors/ARBs together with a fluoroquinolone antibiotic such as ciprofloxacin, gemifloxacin, levofloxacin, moxifloxacin and norfloxacin, contact your doctor to re-evaluate your treatment
- if you have any other heart, liver or kidney problems
- if you take potassium supplements, potassium-containing salt substitutes and potassium sparing diuretics such as spironolactone, triamterene, amiloride
- if you have porphyria
- if you suffer from Addison's disease
- if you have low blood potassium levels

## PATIENT INFORMATION LEAFLET

### PEARINDA PLUS 4

- if you take lithium products
- if you are pregnant or breastfeeding
- if you have severe liver disease or suffer from a condition called hepatic encephalopathy (degenerative disease of the brain)
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren
- if you are being treated with sacubitril/valsartan, a medicine for heart failure
- if you are receiving dialysis, or any other type of blood filtration. Depending on the machine that is used, PEARINDA PLUS 4 may not be suitable for you.

#### Warnings and precautions

##### Take special care with PEARINDA PLUS

PEARINDA PLUS 4 tablets should not be given to children.

The presence of other medical problems may affect the use of PEARINDA PLUS 4.

Tell your doctor, pharmacist or healthcare provider:

- if you take lithium for treatment of mood disorders (see Do not take PEARINDA PLUS 4)
- if you are treated with ACE inhibitors/ARBs together with a fluoroquinolone antibiotic such as ciprofloxacin, gemifloxacin, levofloxacin, moxifloxacin and norfloxacin as he/she will need to re-evaluate your treatment, or if you are elderly
- if you have high or low blood potassium, low blood sodium, or are on a sodium-restricted diet or use salt substitutes which contain potassium
- if you suffer from a collagen disease such as systemic lupus erythematosus or scleroderma, or your immune system is suppressed
- if you have problems with your kidneys or if you are receiving dialysis with high-flux membranes
- if you have a severe allergic reaction with swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing (angioedema). This may occur at any time

## PATIENT INFORMATION LEAFLET

### PEARINDA PLUS 4

during treatment. If you develop such symptoms, you should stop taking PEARIND PLUS 4 and see a doctor immediately

- if you are taking sirolimus, everolimus, temsirolimus and other drugs belonging to the class of so-called mTor inhibitors (used to avoid rejection of transplanted organs)
- if you are taking sacubitril (available as fixed-dose combination with valsartan), used to treat long-term heart failure (see Do not take PEARINDA PLUS 4)
- if you are going to have desensitisation treatment to reduce the effects of an allergy to bee or wasp stings
- if you are to undergo a procedure or test that requires injection of a contrast agent containing iodine
- if you are to undergo dialysis or LDL apheresis (which is removal of cholesterol from your blood by a machine)
- if you have abnormally increased levels of a hormone called aldosterone in your blood (primary aldosteronism)
- if you have liver problems
- if you have had photosensitivity reactions
- if you have heart failure or any other heart problems
- if you have renal artery stenosis (narrowing of the artery supplying the kidney with blood), or a single kidney (see do not take PEARINDA PLUS 4)
- if you have low blood pressure
- if you become dehydrated (volume depleted), e.g. if you were vomiting, or had diarrhoea or heavy sweating, if you are on dialysis, or if you follow a salt restricted diet or use diuretics
- your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals
- if you have had blood vessel problems in your brain (cerebrovascular disease) or ischaemic heart disease
- if you suffer from hardening of the arteries (atherosclerosis)

## PATIENT INFORMATION LEAFLET

### PEARINDA PLUS 4

- if you have bone marrow depression.
- if you have hypertrophic cardiomyopathy (heart muscle disease)
- if you suffer from hyperparathyroidism (overactive parathyroid gland)
- if you suffer from diabetes which is not well controlled
- if you suffer from gout
- if you are of black ethnicity, since you may have a higher risk of angioedema and this medicine may be less effective in lowering your blood pressure than in non-black patients
- if you take lithium or potassium-sparing drugs (spironolactone, triamterene) or potassium supplement, as their use with PEARINDA PLUS 4 should be avoided (see Other medicines and PEARINDA PLUS 4)
- if you are going to have an operation or anaesthesia
- if you have changes in your vision or pain in one or both of your eyes while taking this medicine. This could be a sign that you are developing glaucoma which is characterised by increased pressure in your eye(s). You should discontinue PEARINDA PLUS 4 and seek medical attention.

Athletes should note that this product contains indapamide, which may give a positive reaction in drug tests.

You must tell your doctor if you think that you are (or might become) pregnant. PEARINDA PLUS 4 is not recommended in early pregnancy, and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if used at that stage (see Pregnancy, breastfeeding and fertility).

PEARINDA PLUS 4 is not for use in children as safety and efficacy have not been established.

## PATIENT INFORMATION LEAFLET

### PEARINDA PLUS 4

#### Other medicines and PEARINDA PLUS 4

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

You should not be taking PEARINDA PLUS 4 with:

- lithium (used to treat mania or depression)
- aliskiren (medicine used to treat hypertension) if you have no diabetes mellitus or kidney problems
- ACE inhibitors/ARBs together with a fluoroquinolone antibiotic such as ciprofloxacin, gemifloxacin, levofloxacin, moxifloxacin and norfloxacin
- potassium supplements, potassium-containing salt substitutes, potassium-sparing diuretics (spironolactone, triamterene, amiloride), other medicines which can increase potassium in your body (such as heparin and co-trimoxazole also known as trimethoprim/sulfamethoxazole)
- medicines for the treatment of cancer
- sacubitril/valsartan (used to treat long-term heart failure).

Treatment with PEARINDA PLUS 4 can be affected by other medicines. Make sure to tell your doctor if you are taking any of the following medicines as special care may be required:

- other medicines for treating high blood pressure, angiotensin-II receptor blocker or aliskiren or including diuretics (water tablets)
- medicines for the treatment of diabetes, e.g. insulin and metformin or gliptins
- potassium-sparing medicines used in the treatment of heart failure (eplerenone and spironolactone)
- medicines which are most often used to treat diarrhoea (racecadotril) or avoid rejection of transplanted organs (sirolimus, everolimus, temsirolimus and other medicines belonging to the class of so-called mTor inhibitors)

## PATIENT INFORMATION LEAFLET

### PEARINDA PLUS 4

- vasodilators including nitrates (products that make the blood vessels become wider)
- allopurinol (for the treatment of gout)
- immunosuppressants used for the treatment of auto-immune disorders or following transplant surgery to prevent rejection (e.g. ciclosporin, tacrolimus)
- corticosteroids (for various conditions, including asthma)
- medicines for heart rhythm problems (e.g. procainamide, sotalol, digoxin, quinidine, hydroquinidine, disopyramide, amiodarone)
- anaesthetic medicines
- injectable gold (used to treat rheumatoid polyarthritis)
- sympathomimetic medicines used for the treatment of low blood pressure, shock or asthma (e.g. ephedrine, noradrenaline or adrenaline)
- medicines to treat mental disorders such as depression, anxiety, schizophrenia (e.g. tricyclic antidepressants and neuroleptics, such as amisulpride, sulpiride, sultopride, tiapride, haloperidol, droperidol)
- other medicines that could cause lowering of the blood pressure
- erythromycin (an antibiotic)
- halofantrine (for certain types of malaria)
- vincamine (used to treat symptomatic cognitive disorders in elderly, including memory loss)
- bepridil (used to treat angina pectoris)
- cisapride, diphemanil (used to treat gastric and digestive problems)
- methadone (used to treat addiction)
- mizolastine, astemizole (antihistamines for hay fever or allergies)
- pentamidine (for treatment of some types of pneumonia)
- terfenadine (antihistamine for allergies or hay fever)
- stimulant laxatives e.g. senna
- amphotericin B (for fungal diseases)

## PATIENT INFORMATION LEAFLET

### PEARINDA PLUS 4

- tetracosactide or corticosteroids (cortisone) (for treatment of Crohn's disease)
- iodinated contrast agents (which are given to patients so that blood vessels and organs can be seen clearly on medical scans)
- calcium
- nonsteroidal anti-inflammatory medicines or high dose salicylates (e.g. aspirin)
- anticoagulants
- baclofen (for muscle stiffness)
- trimethoprim (for the treatment of infections).

#### **PEARINDA PLUS 4 with food and drink**

It is recommended that PEARINDA PLUS 4 should be taken once daily before a meal.

Avoid drinking alcohol. Drinking alcohol with PEARINDA PLUS 4 may further lower your blood pressure and may make you feel dizzy or lightheaded.

#### **Pregnancy, breastfeeding and fertility**

If you are pregnant or breastfeeding your baby, 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 4.

PEARINDA PLUS 4 may be harmful to your baby.

You must not take PEARINDA PLUS 4:

- if you are pregnant, planning to become pregnant or if you suspect you are pregnant
- if you are breastfeeding.

Should you become pregnant or contemplate pregnancy while using PEARINDA PLUS 4, consult your doctor without delay. The switch to an alternative treatment should be initiated as soon as possible.

## **PATIENT INFORMATION LEAFLET**

### **PEARINDA PLUS 4**

#### **Driving and using machines**

You may experience dizziness or lightheadedness while taking PEARINDA PLUS 4.

Do not drive, operate machinery, or do anything else that could be dangerous until you know how you react to PEARINDA PLUS 4.

It is not always possible to predict to what extent PEARINDA PLUS 4 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 4 affects them.

#### **PEARINDA PLUS 4 contains lactose**

PEARINDA PLUS 4 contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

### **3. How to take/use PEARINDA PLUS 4**

Do not share medicines prescribed for you with any other person. Always use PEARINDA PLUS 4 exactly as your doctor has told you. You should check with your doctor or pharmacist if you are unsure.

It is recommended that PEARINDA PLUS 4 is taken once daily in the morning before a meal.

Speak to your doctor if you suffer from kidney disease for information on how this medicine should be taken as the usual dosages may not be appropriate for you.

#### **Children:**

PEARINDA PLUS 4 is not suitable for use in children.

## PATIENT INFORMATION LEAFLET

### PEARINDA PLUS 4

Your doctor will tell you how long your treatment with PEARINDA PLUS 4 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 4 is too strong or too weak, tell your doctor or pharmacist.

#### **If you take/use more PEARINDA PLUS 4 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:

- The most likely effect in case of overdose is low blood pressure. If marked low blood pressure occurs (symptoms such as dizziness or faintness), lying down with the legs raised can help.

#### **If you forget/use to take PEARINDA PLUS 4**

It is important to take your medicine every day. However, if you forget to take one or more doses, take another as soon as you remember and then go on as prescribed on a normal daily dose. Do not take a double dose to make up for forgotten individual doses.

#### **If you stop taking/using PEARINDA PLUS 4**

As the treatment for high blood pressure is usually life-long, you should discuss with your doctor before stopping PEARINDA PLUS 4.

#### **4. Possible side effects**

PEARINDA PLUS 4 can have side effects.

Not all side effects reported for PEARINDA PLUS 4 are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while using PEARINDA PLUS, please consult your healthcare provider for advice.

## PATIENT INFORMATION LEAFLET

### PEARINDA PLUS 4

If any of the following happens, stop using PEARINDA PLUS 4 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
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to PEARINDA PLUS 4. 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 dizziness or fainting due to low blood pressure
- bronchospasm (tightening of the chest, wheezing and shortness of breath)
- irregular heartbeat, heart attack, chest pain, stroke
- severe skin reactions including erythema multiforme (a skin rash which often starts with red itchy patches on your face, arms or legs) or intense skin rash, hives, reddening of the skin over your whole body, severe itching, blistering, peeling and swelling of the skin, inflammation of mucous membranes (Stevens- Johnson Syndrome) or other allergic reactions
- inflamed pancreas which may cause severe abdominal and back pain accompanied with feeling very unwell
- yellowing of the skin or eyes (jaundice) which could be a sign of hepatitis, inflammation of the liver
- disease of the brain caused by liver illness (hepatic encephalopathy).

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:

## PATIENT INFORMATION LEAFLET

### PEARINDA PLUS 4

- low potassium levels
- vertigo, tiredness, tinnitus (sensation of noises in the ears)
- low blood pressure
- diarrhoea, nausea, abdominal pain, indigestion, vomiting, dry mouth, taste disturbances, constipation, loss of appetite, anorexia
- itching, rash
- cough, shortness of breath.

#### Less frequent side effects:

- changes in the blood (your doctor may decide to carry out blood tests at regular intervals to monitor for this)
- change in laboratory parameters: high blood level of potassium (reversible on discontinuation), low blood level of sodium, increases in blood urea and blood glucose, increases in serum creatinine, raised plasma calcium levels, gout
- dizziness, headache, pins and needles, changes in mood or sleep, confusion, weakness
- vision disturbances
- blocked or runny nose, sinusitis
- skin rash, various skin disorders including urticaria (hives – raised itchy red spots), purpura (red pinpoint spots on skin), formation of blisters
- muscle cramps
- kidney problems
- sexual disorders
- an excess of eosinophils (a type of white blood cells), lower number of white and red blood cells, lower haemoglobin, lower number of blood platelets
- vasculitis (inflammation of blood vessels)
- eosinophilic pneumonia (a rare type of pneumonia)

## PATIENT INFORMATION LEAFLET

### PEARINDA PLUS 4

- photosensitivity reactions (increased sensitivity of the skin to sun), excess sweating, worsening of psoriasis
- arthralgia (joint pain), myalgia (muscle pain)
- severe kidney problems
- general sense of being unwell, swelling of arms or legs due to fluid retention, fever
- fall.

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

- numbness and pain in fingers or toes (Raynaud's phenomenon)
- short sightedness (myopia), blurred vision
- if you suffer from systemic lupus erythematosus (a type of collagen disease), this might get worse
- high uric acid levels and high sugar levels in the blood, abnormal liver test results.

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 using either of the following links: <https://www.sahpra.org.za/Publications/Index/8> or [sahpra.org.za/document/adverse-drug-reactions-andquality-problem-reporting-form/](https://www.sahpra.org.za/document/adverse-drug-reactions-andquality-problem-reporting-form/).

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

#### 5. How to store PEARINDA PLUS 4

Store all medicines out of reach of children.

## PATIENT INFORMATION LEAFLET

### PEARINDA PLUS 4

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

Keep the blisters in the 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).

#### 6. Contents of the pack and other information

##### What PEARINDA PLUS 4 contains

The active ingredients are perindopril *tert*-butylamine salt and indapamide.

Each tablet contains 4 mg perindopril *tert*-butylamine salt and 1,25 mg of indapamide.

##### The other ingredients are:

Lactose monohydrate, magnesium stearate, microcrystalline cellulose and silica colloidal anhydrous.

##### What PEARINDA PLUS 4 looks like and contents of the pack

PEARINDA PLUS 4: A white capsule shaped tablet with dimensions of 8 mm x 4 mm approximately, bearing a break line on both sides.

PEARINDA PLUS 4: The tablets are available in PA/ALU/PVC/ALU blister packs of 30 tablets in an outer carton.

##### Holder of Certificate of Registration

Pharma Dynamics (Pty) Ltd

1<sup>st</sup> Floor, Grapevine House, Steenberg Office Park

Silverwood Close

Westlake, Cape Town

7945, South Africa

Tel: + 27 21 707 7000

## PATIENT INFORMATION LEAFLET

### PEARINDA PLUS 4

**This leaflet was last revised in**

19 June 2023

[www.pharmadynamics.co.za](http://www.pharmadynamics.co.za)

**Registration number**

A41/7.1.3/0633

**NAMIBIA:**

Pearinda Plus 4: NS2 10/7.1.3/0611