

**PATIENT INFORMATION LEAFLET**  
**PEARINDA PLUS RANGE**

**SCHEDULING STATUS**

**S3**

**PROPRIETARY NAME AND DOSAGE FORM**

**PEARINDA PLUS 2** tablet

**PEARINDA PLUS 4** tablet

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

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- PEARINDA PLUS 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 PEARINDA PLUS CONTAINS**

The active substances are perindopril *tert*-butylamine and indapamide.

PEARINDA PLUS 2: Each tablet contains 2 mg perindopril *tert*-butylamine and 0,625 mg of indapamide.

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

The other ingredients are magnesium stearate, microcrystalline cellulose and silica colloidal anhydrous.

PEARINDA PLUS 2: Contains sugar (lactose monohydrate 64,155 mg per tablet).

PEARINDA PLUS 4: Contains sugar (lactose monohydrate 61, 530 mg per tablet).

**2. WHAT PEARINDA PLUS IS USED FOR**

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

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

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heart failure.

Indapamide is a diuretic (sometimes called a water tablet). Diuretics work by making the kidneys pass more urine out of the body. Both active substances reduce blood pressure and they work together to control blood pressure.

### **3. BEFORE YOU TAKE PEARINDA PLUS**

#### **Do not take PEARINDA PLUS**

- if you are hypersensitive (allergic) to perindopril *tert*-butylamine, or any other ACE inhibitor, or to indapamide or any other sulphonamide or to any of the other ingredients in PEARINDA PLUS (see WHAT PEARINDA PLUS CONTAINS)
- 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 or have had these symptoms in any other circumstances (a condition called angioedema)
- 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)
- 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 suffer from heart failure which is not well controlled
- if you have a severe kidney disorder
- if you are taking potassium-sparing diuretics such as spironolactone, triamterene and amiloride
- if you have porphyria (a rare blood disorder)
- if you have a problem with your adrenal glands called Addison's disease
- if you have low blood potassium levels
- if you have a severe liver disorder
- if you are taking lithium (to treat mood disorders)

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- if you are pregnant or breastfeeding (see Pregnancy and breastfeeding)
- if you are taking aliskiren (a renin inhibitor that decreases blood pressure).

PEARINDA PLUS tablets should not be given to children.

**Take special care with PEARINDA PLUS**

The presence of other medical problems may affect the use of PEARINDA PLUS. Tell your doctor, pharmacist or healthcare provider before taking PEARINDA PLUS:

- 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 are pregnant or become pregnant you should stop taking PEARINDA PLUS and be changed to a different medicine (see Do not take PEARINDA PLUS)
- if you have heart problems or heart failure or problems with your kidney
- if you become dehydrated (volume depleted), e.g. if you were vomiting, or had diarrhoea or heavy sweating, if you are on dialysis
- if you are taking potassium supplements, potassium containing salt substitutes and potassium-sparing diuretics
- if you are on a salt- restricted diet (see Taking other medicines with PEARINDA PLUS)
- if you have liver failure
- 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 diabetes which is not well controlled
- if you suffer from a collagen disease such as systemic lupus erythematosus or scleroderma
- if you have recently had a kidney transplant.
- if you have bone marrow depression
- if you suffer from hyperparathyroidism (an overactive parathyroid gland)
- if you suffer from gout.

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

You should inform your doctor, pharmacist or healthcare provider that you are taking PEARINDA PLUS:

- if you think you are, or might become pregnant as PEARINDA is not recommended in early pregnancy as it may cause serious harm to your baby if used at this stage (see Pregnancy and breastfeeding)
- if you are going to have an operation or anaesthesia
- if you are of black origin since you may have a higher risk of angioedema and PEARINDA PLUS may be less effective in lowering your blood pressure than in non-black patients
- 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 as this medicine is associated with a dry persistent cough
- If you have been told by a doctor that you have low sodium or potassium levels in your blood, or high calcium levels in your blood
- if you experience a high sensitivity to sunlight (photosensitivity)
- if you are an athlete, as the use of PEARINDA PLUS, may result in a positive doping test.

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**Taking PEARINDA PLUS with food and drink**

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

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

**Pregnancy and breastfeeding**

You should not take PEARINDA PLUS if you are pregnant or breastfeeding your baby (see Do not take PEARINDA PLUS). PEARINDA PLUS should not be used in early pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking PEARINDA PLUS.

**Driving and using machinery**

You may experience dizziness or light-headedness while taking PEARINDA PLUS. Do not drive, operate machinery, or do anything else that could be dangerous until you know how PEARINDA PLUS affects you.

**Important information about some of the ingredients of PEARINDA PLUS**

PEARINDA PLUS contains lactose. Patients with rare hereditary conditions of galactose intolerance e.g. galactosaemia or glucose-galactose malabsorption should not take PEARINDA PLUS. PEARINDA PLUS contains lactose which may have an effect on your blood sugar if you have diabetes mellitus.

**Taking other medicines with PEARINDA PLUS**

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

Treatment with PEARINDA PLUS can be affected by the following medicines. Your doctor may need to change your dose and/or take other precautions. These include:

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- contact your doctor to re-evaluate your treatment if you are treated with ACE inhibitors/ Angiotension receptor blockers together with a fluoroquinolone antibiotic such as ciprofloxacin, gemifloxacin, levofloxacin, moxifloxacin and norfloxacin
- lithium (for mania and depression)
- medicines to treat diabetes such as insulin or metformin may further lower blood sugar levels if used with PEARINDA PLUS
- baclofen (to treat muscle stiffness occurring in diseases such as multiple sclerosis) may cause blood pressure to fall lower than normal
- other medicines for treating high blood pressure, including diuretics (water tablets) may decrease your blood pressure further when taken with PEARINDA PLUS
- other blood pressure lowering medicines may increase the antihypertensive effects of PEARINDA PLUS
- medicines used to treat mental illnesses such as depression, anxiety, schizophrenia (tricyclic antidepressants, neuroleptics) may lower your blood pressure further when taken with PEARINDA PLUS
- 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 and may reduce your potassium levels
- Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) and indomethacin decrease the antihypertensive effects of PEARINDA PLUS
- 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
- if you are going to have an operation or anaesthesia as the effect of the anaesthetic may be increased
- allopurinol (to treat gout), immunosuppressants used to treat auto-immune disorders or following transplant surgery to prevent rejection, and medicines to treat cancer, may increase your risk of

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infection due to decreased white blood cells if used with PEARINDA PLUS

- gold salts, especially given intravenously to treat rheumatoid arthritis may cause facial flushing, nausea, vomiting and low blood pressure if used with PEARINDA PLUS
- medicines that reduce blood potassium levels including stimulant laxatives such as senna, amphotericin B (for fungal diseases) may reduce your blood potassium levels
- calcium salts taken with PEARINDA PLUS can cause increased blood levels of calcium as less calcium is eliminated from the body in the urine
- medicines for sinus or nasal congestion, colds, low blood pressure, glaucoma shock or asthma such as noradrenaline, adrenaline, phenylephrine, brimonidine and salbutamol may decrease the antihypertensive effect of PEARINDA PLUS
- 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)
- metformin (for diabetes) may cause lactic acidosis, a build-up of lactic acid in the body which may make you feel nauseous and weak
- medicines that prevent the blood from clotting such as coumarin, indandione and warfarin may reduce the antihypertensive effect if used with PEARINDA PLUS
- digoxin (for the treatment of heart problems) may have harmful effects if your blood potassium levels are low
- medicines for heart rhythm problems that induce “*torsades de pointes*” (irregular heartbeat), such as procainamide, sotalol, digoxin, quinidine, hydroquinidine, disopyramide, amiodarone may increase the risk of dysrhythmias (irregular heartbeat) if your blood potassium levels are low
- some neuroleptics (used to treat mental illnesses) such as chlorpromazine, trifluoperazine, pimozide, sulpiride, tiapride and haloperidol may cause irregular heartbeats if low blood potassium levels are present
- medicines such as bepridil (to treat angina), intravenous erythromycin (an antibiotic), halofantrine (for certain types of malaria) and pentamidine (for treatment of some types of pneumonia), vimcaine (to treat brain disorders in the elderly) and methadone may cause irregular heartbeats if you have low blood potassium

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- PEARINDA PLUS may cause low blood potassium levels when used with medicines used for muscle paralysis during mechanical ventilation or surgery resulting in increased muscle paralysis
- ciclosporin may cause increased creatinine levels which may indicate possible kidney problems.

#### 4. HOW TO TAKE PEARINDA PLUS

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

Always take PEARINDA PLUS exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. Your doctor will tell you how long your treatment will last. If you have the impression that the effect of PEARINDA PLUS is too strong or too weak, tell your doctor or pharmacist.

The usual dose of PEARINDA PLUS 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 decide on the correct dose for you.

#### ***Renal insufficiency (renal failure)***

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

PEARINDA PLUS is not suitable for use in children.

#### **If you take more PEARINDA PLUS 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. Take this leaflet and any remaining tablets with you, so that the doctor knows what you have taken.

#### **If you forget to take a dose of PEARINDA PLUS**

It is important to take PEARINDA PLUS every day. However, if you forget to take one or more doses,



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take the missed dose as soon as you remember and then continue to take the next tablet at the usual time. Do not take a double dose to make up for the forgotten individual doses.

**5. POSSIBLE SIDE EFFECTS**

**PEARINDA PLUS** can have side effects.

If any of the following happens, stop taking PEARINDA PLUS 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
- skin rash, itching
- dizziness or fainting
- toxic epidermal necrolysis (a rare, life-threatening skin condition).

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to PEARINDA PLUS. 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 centre of your chest (heart attack) or drooping face, arm weakness and slurred speech (stroke)
- cough
- light-headedness due to low blood pressure
- yellowing of the skin and eyes (jaundice), inflammation of the liver
- severe fluid or blood loss as a result of serious cuts or wounds, injuries, internal bleeding, prolonged or excessive diarrhoea, excessive vomiting or sweating.

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

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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)
- tiredness
- diarrhoea, nausea, abdominal pain, indigestion, vomiting, constipation, severe stomach pain, changes in your sense of taste, dry mouth, anorexia
- abnormal physical weakness or lack of energy.

**Less frequent side effects**

- anaemia (pale skin, tiredness, dizziness, shortness of breath)
- thrombocytopenia (bleeding gums or nose, blood in urine or stool, easily bruised)
- signs of infection such as sore throat, fever and chills (agranulocytosis and neutropenia)
- low sodium levels (headache, nausea, vomiting, tiredness, muscle spasms, seizures)
- fatigue or weakness, numbness or tingling, nausea or vomiting, chest pain, palpitations or skipped heartbeats (high potassium levels)
- headaches, dizziness, muscle cramps and weakness
- vision disturbances
- inflammation of the pancreas and liver (stomach pain, fever, nausea)
- alopecia (spot baldness), psoriasis (chronic skin condition that causes itchy or sore patches of thick red skin with silvery scales, sensitivity to light)
- kidney problems (swollen ankles, feet or hands, weight loss, poor appetite)
- impotence.

**Side effects with unknown frequency**

- vasculitis (inflammation of the blood vessels), myalgia (muscle pain), arthralgia (joint pain), excess of eosinophilia (a type of white blood cells)
- changes in mood or sleep, confusion
- tinnitus (ringing or buzzing in the ears)

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- increased blood sugar levels
- change in parameters: high blood level of potassium, increased blood creatinine (kidney problems), increased uric acid (gout), increased liver enzymes (liver inflammation or damage).

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

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

#### 6. STORING AND DISPOSING OF PEARINDA PLUS

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

Keep the blisters in the carton until required for use.

Do not store your medicine in the bathroom.

Do not take PEARINDA PLUS after the expiry date stated on the carton.

Return any expired or unused medicine to your pharmacist for safe disposal.

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

Store all medicines out of reach of children.

#### 7. PRESENTATION OF PEARINDA PLUS

\*PEARINDA PLUS 2: The tablets are available in Alu blister packs of 30's, contained in a printed outer carton.

PEARINDA PLUS 4: The tablets are available in Alu blister packs of 30's contained in a printed outer carton.

\*Not all strengths are marketed in South Africa.

#### 8. IDENTIFICATION OF PEARINDA PLUS

PEARINDA PLUS 2: A white capsule shaped tablet with dimensions of 8 x 4 mm approximately, bearing a break-line on both sides.

PEARINDA PLUS 4: A white capsule shaped tablet with dimensions of 8 x 4 mm approximately, bearing

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a break-line on both sides.

**9. REGISTRATION NUMBERS**

PEARINDA PLUS 2: A41/7.1.3/0632

PEARINDA PLUS 4: A41/7.1.3/0633

**10. NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF REGISTRATION HOLDER**

Pharma Dynamics (Pty) Ltd.

1st Floor, Grapevine House

Steenberg Office Park

Silverwood Close

Westlake, 7945

Cape Town, South Africa

Tel: + 27 21 707 7000

**11. DATE OF PUBLICATION**

Date of registration: 30 April 2010

Date of latest approval: 02 January 2020

<b>NAM</b>		
PEARINDA PLUS 2:	NAM <span style="border: 1px solid black; padding: 0 2px;">NS2</span>	10/7.1.3/0610
PEARINDA PLUS 4:	NAM <span style="border: 1px solid black; padding: 0 2px;">NS2</span>	10/7.1.3/0611