

## Patient Information Leaflet

### SCHEDULING STATUS:

S3

### PROPRIETARY NAME AND DOSAGE FORM:

**PEARINDA PLUS 2** (Tablet) \* Not marketed.

**PEARINDA PLUS 4** (Tablet)

### Read this entire 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 ingredients are:*

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

**PEARINDA PLUS 4:** Each tablet contains 4 mg perindopril *tert*-butylamine salt 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 ingredients, i.e. perindopril and indapamide.

Perindopril belongs to a class of medicines called ACE inhibitors.

Indapamide is a diuretic (sometimes called a water tablet).

Both active ingredients 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 **PEARINDA PLUS** or any other ACE inhibitor, or to sulphonamides or to any of the other ingredients of **PEARINDA PLUS**.
- 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.
- have hereditary or idiopathic angioedema.
- 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.
- 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.
- have any other heart, liver or kidney problems.
- take potassium supplements, potassium-containing salt substitutes and potassium sparing diuretics such as spironolactone, triamterene, amiloride.
- have porphyria.
- suffer from Addison's disease.
- have low blood potassium levels.
- take lithium products.
- if you are pregnant or breastfeeding.

**PEARINDA PLUS** tablets should not be given to children.

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

**Tell your doctor, pharmacist or healthcare provider if you:**

- 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.  
have blood vessel problems in your brain (cerebrovascular disease) or ischaemic heart disease.
- 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.
- have high or low blood potassium, low blood sodium, or are on a sodium-restricted diet or use salt substitutes which contain potassium.
- suffer from a collagen disease such as systemic lupus erythematosus or scleroderma, or your immune system is suppressed.
- have low blood pressure.
- have bone marrow depression.
- suffer from hardening of the arteries (atherosclerosis).
- suffer from gout.
- have any other heart, liver or kidney problems.
- suffer from diabetes which is not well controlled.
- are allergic to lactose.

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

- are going to have an operation or anaesthesia.
- are going to have desensitisation treatment to reduce the effects of an allergy to bee or wasp stings.

- are to undergo a procedure or test that requires injection of a contrast agent containing iodine.

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

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

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

**Driving and using machinery:**

You may experience dizziness or lightheadedness while taking **PEARINDA PLUS**. Do not drive, operate machinery, or do anything else that could be dangerous until you know how you react on **PEARINDA PLUS**.

Before you begin using any new medicine (prescription or non prescription) or if you develop any new medical problem while you are using **PEARINDA PLUS**, check with your doctor, pharmacist or other healthcare provider.

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

**PEARINDA PLUS** contains lactose. Patients who are lactose intolerant or have rare hereditary problems of galactose intolerance, Lapp-lactase deficiency or glucose-galactose malabsorption should not take **PEARINDA PLUS**.

**Taking other medicines with PEARINDA PLUS:**

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

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **PEARINDA PLUS** with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare provider, for advice.

In particular, you should check with your doctor, pharmacist or other healthcare provider, if you are taking any of the following to be sure that it is safe to take **PEARINDA PLUS** at the same time:

- 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.
- other medicines for treating high blood pressure including diuretics (water tablets).
- other medicines that could cause lowering of the blood pressure .
- potassium supplements, potassium-containing salt substitutes and potassium-sparing diuretics (e.g. spironolactone, triamterene or amiloride).
- non-steroidal anti-inflammatory medicines.
- tricyclic antidepressants.
- corticosteroids (for various conditions, including asthma).
- medicines for the treatment of diabetes, e.g. insulin and metformin.
- baclofen (for muscle stiffness).
- medicines for heart rhythm problems (e.g. procainamide, sotalol, digoxin, quinidine, hydroquinidine, disopyramide, amiodarone).
- allopurinol (for treatment of gout).
- medicines for the treatment of cancer.
- immunosuppressants, e.g. cyclosporine.
- erythromycin (an antibiotic).
- halofantrine (for certain types of malaria).

- pentamidine (for treatment of some types of pneumonia).
- terfenadine (antihistamine for allergies or hayfever).
- stimulant laxatives e.g. senna.
- amphotericin B (for fungal diseases).
- tetracosactide or corticosteroids (cortisone) (for treatment of Crohn's disease).
- calcium.
- anticoagulants.

#### **4. HOW TO TAKE PEARINDA PLUS:**

Always take **PEARINDA PLUS** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

If you have the impression that the effect of **PEARINDA PLUS** is too strong or too weak, talk to your doctor or pharmacist. Do not share medicines prescribed for you with any other person.

It is recommended that **PEARINDA PLUS** 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.

**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 PEARINDA PLUS:**

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.

## 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:

- hives
- severe stomach pain
- difficulty in breathing
- swelling of hands, feet, ankles, face, lips, mouth or throat
- unusually fast or irregular heartbeat. These could be signs of angioedema which is a serious reaction that can occur with all medicines of this type (ACE inhibitors).

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 if you notice any of the following:

The following frequent side effects may occur:

- cough
- low blood pressure
- vertigo
- tiredness
- low potassium levels
- diarrhoea, nausea, abdominal pain, indigestion, vomiting, dry mouth, taste disturbances, constipation, loss of appetite
- itching.

*The following side effects occur less frequently:*

- changes in the blood (your doctor may decide to carry out blood tests at regular intervals to monitor for this)

- headaches
- dizziness
- pins and needles
- irregular heartbeat, heart attack, chest pain, stroke
- changes in mood or sleep, confusion
- gout, inflammation of the pancreas
- sexual disorders
- kidney problems, jaundice, inflammation of the liver
- tightening of the chest, wheezing and shortness of breath
- blocked or runny nose, sinusitis
- muscle cramps and weakness
- skin rash, various skin disorders
- vision disturbances.

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

#### **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 which is clearly marked on the blister and outside of the box.

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.