

SCHEDULING STATUS:**S3****PROPRIETARY NAME AND DOSAGE FORM:****PEARINDA 2 mg** tablets**PEARINDA 4 mg** tablets**PEARINDA 8 mg** tablets**Read all of this leaflet carefully before you start taking PEARINDA**

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

The active substance is perindopril *tert*-butylamine salt.

PEARINDA 2: Each tablet contains 2 mg perindopril *tert*-butylamine salt.

PEARINDA 4: Each tablet contains 4 mg perindopril *tert*-butylamine salt.

PEARINDA 8: Each tablet contains 8 mg perindopril *tert*-butylamine salt.

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

PEARINDA 2: Contains sugar (lactose monohydrate 31,39 mg per tablet).

PEARINDA 4: Contains sugar (lactose monohydrate 62,78 mg per tablet).

PEARINDA 8: Contains sugar (lactose monohydrate 125,56 mg per tablet).

2. WHAT PEARINDA IS USED FOR

PEARINDA belongs to a class of medicines called ACE inhibitors. ACE stands for angiotensin converting enzyme. 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.

PEARINDA is used to treat:

- Mild to moderate high blood pressure (hypertension)
- Congestive heart failure (a condition where the heart is unable to pump enough blood to meet the body's needs), not adequately controlled by conventional therapy.

3. BEFORE YOU TAKE PEARINDA

Do not take **PEARINDA**

- if you are hypersensitive (allergic) to perindopril or any other ACE inhibitor, or to any of the other ingredients in the tablet (see **WHAT PEARINDA CONTAINS**)
- if you 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) treatment or have had these symptoms in any other circumstances (this is a condition called angioedema)
- if you have narrowing of the main blood vessel leading from the heart, 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
- if you have any other heart or kidney problems
- if you have porphyria

- if you are pregnant or breastfeeding, or intend becoming pregnant

PEARINDA tablets should not be given to children.

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

Talk to your doctor, pharmacist or healthcare provider before taking **PEARINDA**:

- 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 blood vessel problems in your brain (cerebrovascular disease) or ischaemic heart disease
- 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
- if you have high 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
- if you have bone marrow depression
- if you have any other heart or liver or kidney problems
- if you suffer from diabetes which is not well controlled
- if you are allergic to lactose.

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

- if you are going to have an operation or anaesthesia
- 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 to remove cholesterol from your blood by a machine (LDL apheresis).

Taking PEARINDA with food and drink:

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

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

Pregnancy and breastfeeding:

You should not take **PEARINDA**:

- 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 consult your healthcare provider for advice before taking **PEARINDA**.

Driving and using machinery:

You may experience dizziness or light-headedness while taking **PEARINDA**. Do not drive, operate machinery, or do anything else that could be dangerous until you know how you react on **PEARINDA**. Before you begin using any new medicine (prescription or non prescription) or if you develop any new medical problem while you are using this medicine, check with your doctor, pharmacist or other healthcare provider.

Important information about some of the ingredients of PEARINDA:

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

Taking other medicines with PEARINDA:

Always tell your healthcare provider 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** 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** 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)
- lithium (for mania or depression)
- non-steroidal anti-inflammatory medicines.

4. HOW TO TAKE PEARINDA

Always take **PEARINDA** 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** is too strong or too weak, tell your doctor or pharmacist. Do not share medicines prescribed for you with any other person.

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

Mild to moderate high blood pressure (hypertension)

The recommended starting dose is 4 mg once daily, which can be increased to a single dose of 8 mg if necessary after one month of treatment.

In elderly patients and if you have certain other conditions, a starting dose of 2 mg will be used, which can be increased according to response to a maximum of 8 mg once daily.

Insulin and non-insulin dependent diabetics can be treated with the usual doses.

Congestive heart failure

The treatment should be initiated at a low dose under close medical supervision. The initial dose is 2 mg as a single dose in the morning. This may be increased to 4 mg once daily as a maintenance dose.

If you are taking water tablets (diuretics), your doctor may decide to reduce or even discontinue these at the beginning of your treatment with **PEARINDA**.

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

PEARINDA is not suitable for use in children.

If you take more PEARINDA than you should:

In the event of overdose, 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:

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 the forgotten individual doses.

5. POSSIBLE SIDE EFFECTS

PEARINDA can have side effects. If any of the following happens, stop taking **PEARINDA** and tell your doctor immediately or go the casualty department at your nearest hospital:

- hives
- severe stomach pain;
- swelling of hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing

- dizziness or fainting;
- 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**. 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
- shortness of breath
- light-headedness due to low blood pressure
- headaches
- pins and needles
- vertigo
- tiredness
- diarrhoea, nausea, abdominal pain, indigestion, vomiting, constipation
- taste disturbances
- muscle cramps and weakness
- skin rash
- itching
- vision disturbances
- ringing sound in the ears.

The following side effects occur less frequently:

- Changes in your blood (your doctor may decide to carry out blood tests at regular intervals to monitor for this), irregular heart beat
- heart attack
- chest pain

- stroke
- changes in mood or sleep
- confusion
- dry mouth
- 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
- eosinophilic pneumonia (a rare type of pneumonia)
- sweating.

Not all side effects reported for **PEARINDA** are included in this leaflet.

Should your general health worsen while taking **PEARINDA**, please consult your 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

- Store at or below 25 °C.
- Keep the blisters in the carton until required for use.
- Do not store your medicine in the bathroom.

Do not take **PEARINDA** 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