APPROVED PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

PEARINDA 4 tablet

PEARINDA 8 tablet

Perindopril *tert*-butylamine.

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

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

Read all of this leaflet carefully before you start taking PEARINDA

- 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 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

APPROVED PATIENT INFORMATION LEAFLET

1. What PEARINDA is and what it is used for

PEARINDA contains the active substance perindopril tert-butylamine which belongs to a class of medicines called ACE inhibitors (angiotensin converting enzyme inhibitor). Perindopril 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

- it reduces the risk of damaging the heart muscle in patients without heart failure, with a history of angina (a condition marked by severe pain in the chest, often also spreading to the shoulders, arms and neck, owing to an inadequate blood supply to the heart) and heart attacks.

2. What you need to know before you take PEARINDA

Do not take PEARINDA:

- if you are hypersensitive (allergic) to perindopril *tert*-butylamine or any other ACE inhibitor, or to any of the ingredients of PEARINDA (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 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 (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/ARBs together with a fluoroquinolone antibiotic such as ciprofloxacin, gemifloxacin, levofloxacin, moxifloxacin and norfloxacin

- if you have any other heart or kidney problems
- if you are taking potassium supplements, potassium containing salt substitutes and potassium-sparing diuretics medicines that increase removal of sodium and reduce potassium removal through the urine e.g. spironolactone, triamterene and amiloride. These medicines are used as additional therapy, together with other medicines in the treatment of hypertension and management of congestive heart failure
- if you have porphyria
- if you are taking lithium (to treat mood disorders)
- if you are taking aliskiren (a renin inhibitor that decreases blood pressure)
- if you are pregnant or breastfeeding, or intend becoming pregnant (see Pregnancy and breastfeeding)
- if you have taken or are currently taking sacubutril/valsartan, a medicine for heart failure, as the risk of angioedema (rapid swelling under the skin in an area such as the throat) is increased.

PEARINDA tablets should not be given to children.

APPROVED PATIENT INFORMATION LEAFLET

Warnings and precautions

Take special care with PEARINDA

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

- contact your doctor to re-evaluate your treatment if you are treated with ACE inhibitors/ARBs 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 and be changed to a different medicine (see Do not take PEARINDA)
- if you have high blood potassium, low blood sodium, or are on a salt-restricted diet or use salt substitutes which contain potassium
- if you have any heart or liver problems
- 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 become dehydrated (volume depleted), e.g. if you were vomiting, or had diarrhoea or heavy sweating, if you are on dialysis, or if you use diuretics (water tablets)
- if you receive kidney dialysis
- 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 are taking any of the following medicines, the risk of angioedema is increased:
    - racecadotril (used to treat diarrhoea)
    - sirolimus, everolimus, temsirolimus and other medicines belonging to a class of so-called mTor inhibitors (used to avoid rejection of transplanted organs
    - sacubitril (available as fixed dose combination with valsartan), used to treat long term heart failure.

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

- 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 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, as this medicine is associated with a dry persistent cough.

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

Other medicines and PEARINDA

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.) Treatment with PEARINDA can be affected by the following medicines. Your doctor may need to change your dose and/or take other precautions. These include:

- a fluoroquinolone antibiotic such as ciprofloxacin, gemifloxacin, levofloxacin, moxifloxacin and norfloxacin, as this may lead to severe kidney damage
- potassium-sparing medicines (e.g. spironolactone, triamterene, amiloride), potassium supplements or potassium-containing salt substitutes
- lithium (for mania or depression)
- aliskiren (a direct renin inhibitor used to treat high blood pressure) may result in low blood pressure, low potassium levels and reduced kidney function when used with PEARINDA

- other medicines for treating high blood pressure, including diuretics (water tablets)
- other blood pressure lowering medicines, including Angiotensin II receptor blockers
- estramustine (used in cancer therapy)
- sacubitril/valsartan used to treat long-term heart failure
- co-trimoxazole (used to treat certain bacterial infections, such as pneumonia)
- potassium-sparing medicines used in the treatment of heart failure: eplerenone and spironolactone
- medicines used to treat diarrhoea (racecadotril) or avoid rejection of transplanted organs (sirolimus, everolimus, temsirolimus) and other drugs belonging to the class of so-called mTor inhibitors
- baclofen (used to treat muscle stiffness in disease such as multiple sclerosis)
- aspirin (acetylsalicylic acid) and thrombolytics (used to prevent clot formation)
- medicines used to decrease the rate and force of heart contractions and lower high blood pressure (beta-blockers)
- nitrate medicines used for treating or preventing chest pain (angina)

APPROVED PATIENT INFORMATION LEAFLET

- Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) decrease the antihypertensive effects of PEARINDA
- medicines for treating diabetes, such as insulin or metformin, may further lower blood sugar levels if used with PEARINDA
- medicines used to treat mental illnesses such as depression, anxiety, schizophrenia (tricyclic antidepressants, neuroleptics) may further lower your blood pressure when taken with PEARINDA
- medicines for low blood pressure, shock or asthma, such as noradrenaline and adrenaline (sympathomimetics medicines)
- medicine used to prevent organ rejection after a kidney, heart or liver transplant or for treatment of severe psoriasis or severe rheumatoid arthritis (ciclosporin)
- digoxin (a cardiac stimulant)
- medicines used to treat anaemia caused by chemotherapy or chronic kidney disease (epoetins)
- Interleukin-3 (a protein that stimulates the immune system to develop mast cells, a type of white blood cell, and bone-marrow cells)
- gold salts, especially with intravenous administration (used to treat symptoms of rheumatoid arthritis).

PEARINDA with food and drink

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

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.

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

Driving and using machines

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 PEARINDA affects you.

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

PEARINDA contains lactose

PEARINDA contains lactose. Patients with the rare hereditary conditions of lactose or galactose intolerance should not take PEARINDA.

PEARINDA contains lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

3. How to take PEARINDA

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

The usual dose of PEARINDA 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.

APPROVED PATIENT INFORMATION LEAFLET

Adults:

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 a month of treatment.

If you are 65 years or older, the usual starting dose is 2 mg once daily, which can be increased to a maximum of 8 mg daily if necessary.

If you have insulin or non-insulin dependent diabetes mellitus, you can be treated with the usual doses.

Congestive heart failure

Treatment should be started at a low dose under close medical supervision. The starting dose is 2 mg as a single dose in the morning. This may be increased to 4 mg daily as a maintenance dose.

If you are taking water tablets (diuretics), your doctor may decide to reduce or even stop these medicines before you start taking PEARINDA to prevent a fall in your blood pressure.

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

Children:

PEARINDA is not suitable for use in children.

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

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

If you take more PEARINDA 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.

Symptoms of overdose may include:

- severe low blood pressure, electrolyte disturbances, kidney failure, hyperventilation, irregular heartbeat, palpitations, dizziness, anxiety and cough.

If you forget to take PEARINDA

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

If you stop taking PEARINDA

Do not stop taking PEARINDA without talking to your doctor. Medicines for high blood pressure or heart failure will normally have to be taken for the rest of your life. If you stop taking PEARINDA, your condition may get worse.
If you have any further questions on the use of PEARINDA, ask your doctor or pharmacist.

4. Possible side effects

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

APPROVED PATIENT INFORMATION LEAFLET

If any of the following happens, stop using PEARINDA 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
- 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. 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 or dizziness due to low blood pressure

- yellowing of the skin and eyes (jaundice), inflammation of the liver
- change in parameters: high blood levels of potassium (fatigue or weakness, numbness or tingling, chest pain, palpitations or skipped heart beats), low levels of sodium (headache, tiredness, muscle spasms and increased blood creatinine (kidney problems)
- 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)
- inflammation of the pancreas (stomach pain that spreads to your back or feels worse after eating, fever, nausea)
- severe kidney problems including low urine output, not passing urine, abnormal quantities of protein in the urine, kidney failure.

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:

- headaches, vertigo, pins and needles, tiredness
- vision disturbances
- tinnitus (ringing or buzzing in the ears)
- diarrhoea, nausea, abdominal pain, indigestion, vomiting, constipation, severe stomach pain, changes in your sense of taste
- rash, itching
- muscle cramps
- abnormal physical weakness or lack of energy.

Less frequent side effects:

- changes in your blood values such as lower number of white and red blood cells, lower haemoglobin, lower number of blood platelets (your doctor may decide to carry out blood tests at regular intervals to monitor for this)
- excess of eosinophilia (a type of white blood cells that fight infection)
- hypoglycaemia (low blood sugar level)
- changes in mood or sleep, confusion
- vasculitis (inflammation of blood vessels)
- sexual disorders
- kidney problems (swollen ankles, feet or hands, weight loss,

poor appetite)

- dry mouth
- blocked or runny nose, pneumonia
- sweating, hives
- joint pain, muscle pain
- nausea, vomiting, pain in the upper right section of the stomach and yellowing of skin which are signs of an inflamed liver (hepatitis), increased level of liver enzymes (liver inflammation or damage) and high level of serum bilirubin
- chest pain, general feeling of discomfort, illness, or unease, leg or arm swelling caused by the retention of fluid in the tissues, fever
- fall.

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

- chest infection (eosinophilic pneumonia, a rare type of pneumonia), sinusitis (sinus infection)
- high blood level of potassium, low level of sodium, increased blood urea and increased blood creatinine

- alopecia (spot baldness), psoriasis (chronic skin condition that causes itchy or sore patches of thick red skin with silvery scales), sensitivity to light.

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 or pharmacist or nurse. You can also report side effects to SAHPRA via the online service for adverse drug reaction reporting by following the link: https://www.sahpra.org.za/Publications/Index/8.

An email can be sent directly to the company, pharmacovigilance@pharmadynamics.co.za, to ensure safety of the product.

By reporting side effects, you can help provide more information on the safety of PEARINDA.

5. How to store PEARINDA

Store all medicines out of reach of children.

Store at or below 25 °C

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).

6. Contents of the pack and other information

What PEARINDA contains

The active ingredient is perindopril *tert*-butylamine.

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

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

The other ingredients are:

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

What PEARINDA looks like and contents of the pack

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

PEARINDA 8: A white round convex tablet, with a diameter of 8 mm approximately, bearing a break-line on one side.

APPROVED PATIENT INFORMATION LEAFLET

PEARINDA 4: The tablets are available in PA-Alu-PVC/Alu foil blister packs of 30's.

PEARINDA 4: The tablets are available in PA-Alu-PVC/Alu foil blister packs of 30's.

Holder of Certificate of Registration

Pharma Dynamics (Pty) Ltd

1st Floor, Grapevine House, Steenberg Office Park

Silverwood Close

Westlake, Cape Town

7945, South Africa

Tel: + 27 21 707 7000

This leaflet was last revised in

06 June 2023

www.pharmadynamics.co.za

Registration number

PEARINDA 4: A41/7.1.3/0649

PEARINDA 8: A41/7.1.3/0650

APPROVED PATIENT INFORMATION LEAFLET

NAM

PEARINDA 4: NS2 10/7.1.3/0476

PEARINDA 8: NS2 10/7.1.3/0477

Reference: Proposed Professional Information for Medicines for Human Use for PEARINDA

02: SAHPRA Guideline for PIL for Human Medicines version *2019_04_12vF*