PATIENT INFORMATION LEAFLET

PEARLOC RANGE

SCHEDULING STATUS:

S3

PEARLOC 4 mg/5 mg tablets

PEARLOC 4 mg/10 mg tablets

PEARLOC 8 mg/5 mg tablets

PEARLOC 8 mg/10 mg tablets

Perindopril tert-butylamine and amlodipine

Sugar free

Essentially 'sodium free'.

Read all of this leaflet carefully before you start taking PEARLOC

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist, nurse or other healthcare provider.
- PEARLOC 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 PEARLOC is and what it is used for
2. What you need to know before you take PEARLOC
3. How to take PEARLOC
4. Possible side effects
5. How to store PEARLOC
6. Contents of the pack and other information

1. What PEARLOC is and what it is used for

PEARLOC is a combination of two active ingredients, perindopril and amlodipine.
Perindopril is an ACE (angiotensin converting enzyme) inhibitor. Amlodipine is a calcium antagonist (which belongs to a class of medicines called dihydropyridines). Together they work to widen and relax the blood vessels, which results in a reduction of blood pressure.

PEARLOC is prescribed for treatment of high blood pressure (hypertension).
Patients already taking perindopril and amlodipine from separate tablets may instead receive one tablet of PEARLOC which contains both ingredients.

2. What you need to know before you take PEARLOC

Do not take PEARLOC:

- if you are hypersensitive (allergic) to perindopril, any other ACE inhibitor, amlodipine or any other dihydropyridine derivative, or to any of the ingredients of PEARLOC (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 (a condition called angioedema) or if you or a member of your family have had these symptoms in any other circumstances
- if you have cardiogenic shock or hypertrophic obstructive cardiomyopathy (HOCM) (when the heart is unable to supply sufficient blood to the body), aortic stenosis (narrowing of the main blood vessels leading from the heart)
- if you have severe kidney disorder, have a single kidney or narrowing of the artery supplying the kidney with blood (renal or bilateral artery stenosis)
- if you are treated with ACE inhibitors/angiotensin receptor blockers together with a fluoroquinolone antibiotic such as ciprofloxacin, gemifloxacin, levofloxacin, moxifloxacin and norfloxacin, contact your doctor to re-evaluate treatment

- if you are taking potassium-sparing diuretics (water tablets) such as spironolactone, triamterene and amiloride, potassium salts
- if you have porphyria (a rare blood disorder)
- if you are taking lithium (to treat mood disorders)
- if you are taking aliskiren (a renin inhibitor that decreases blood pressure)
- if you have severe low blood pressure (hypotension)
- if you suffer from heart failure which is not well controlled after a heart attack
- if you are pregnant or breastfeeding your baby
- if you are taking sacubitril/valsartan, a medicine used to treat a type of long-term (chronic) heart failure in adults, as the risk of angioedema (rapid swelling under the skin in an area such as the throat) is increased
- if you are having any type of treatment that involves filtering your blood, for example the removing of cholesterol from your blood or dialysis. Depending on the machine that is used, PEARLOC may not be suitable for you
- in combination with grapefruit juice.

Warnings and precautions

Take special care with PEARLOC:

Talk to your doctor or pharmacist before taking PEARLOC:

- if you are taking medicines belonging to the class of mechanistic target of rapamycin (mTOR) inhibitors, used to avoid rejection of transplanted organs (e.g. sirolimus, everolimus, temsirolimus) or racecadotril (to treat diarrhoea), as there may be an increased risk for angioedema (e.g. swelling of the airways or tongue)
- if you become dehydrated (volume depleted), e.g. if you were vomiting, or had diarrhoea or heavy sweating
- if you suffer from mitral valve stenosis (narrowing of the heart's mitral valve, blocking blood flow) or hypertrophic cardiomyopathy (heart muscle disease) or renal artery

stenosis (narrowing of the artery suppling the kidney with blood)

- if you have severe liver disease or liver failure
- if you are of black origin you may have a higher risk of angioedema (swelling of the lower layer of skin and tissue) and PEARLOC may be less effective in lowering your blood pressure than in non-black patients
- if you are on a salt restricted diet or use salt substitutes which contain potassium
- if you are taking heparin (to thin your blood) or dantrolene (to reduce muscle pain and stiffness)
- if you have diabetes, or are insulin dependent
- if you are undergoing dialysis
- if you have heart failure (a condition where the heart cannot pump blood well)
- if you are elderly and your dose needs to be increased. This should take place with care
- if you are taking other medicines such as anti-fungal medicines (ketoconazole, itraconazole) or protease inhibitors used to treat human immunodeficiency virus (HIV) (ritonavir). Using these medicines together with PEARLOC may decrease the blood pressure even further (see Other medicines and PEARLOC).

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

- if you are to undergo a procedure to remove cholesterol from your blood by a machine (low-density lipoprotein (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 PEARLOC as this medicine is associated with a dry persistent cough
- if you are going to have an operation or anaesthesia.

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

Other medicines and PEARLOC

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

- aliskiren (a direct renin inhibitor) may result in low blood pressure, low blood potassium levels and reduced kidney function when used with PEARLOC (see Do not take PEARLOC)
- sacubitril/valsartan (a medicine used to treat a type of long-term heart failure in adults), as the risk of angioedema (rapid swelling under the skin in an area such as the throat) is increased (see Do not take PEARLOC)
- estramustine (to treat some types of prostate cancer) may increase the risk of unwanted side effects
- taking co-trimoxazole (an antibiotic) with PEARLOC may increase the levels of potassium in your blood
- fluoroquinolone antibiotics when taken with PEARLOC may cause kidney problems (see Do not take PEARLOC)
- potassium supplements, potassium-containing salt substitutes and potassium-sparing diuretics (water tablets) such as spironolactone, triamterene or amiloride
- lithium (for mania and depression)

- ciclosporin may cause increased creatinine levels which may indicate possible kidney problems and PEARLOC may alter the amount of this medicine in your blood
- heparin (to thin your blood) may affect the electrolyte balance, your doctor may want to monitor these levels throughout treatment with PEARLOC
- Nonsteroidal anti-inflammatory drugs (NSAIDs), including aspirin in high doses, and indomethacin decrease the antihypertensive effects of PEARLOC
- medicines to treat diabetes such as insulin, may further lower blood sugar levels if used with PEARLOC
- other medicines for treating high blood pressure, including diuretics (water tablets) may decrease your blood pressure further when taken with PEARLOC
- tacrolimus, sirolimus, temsirolimus and everolimus (medicines used to change the way your immune system works) may cause unwanted side effects and PEARLOC may increase the levels of these medicines in your blood
- medicines used to lower blood sugar levels (linagliptin, saxagliptin, sitagliptin, vildagliptin) may cause unwanted side effects
- gold salts, especially given intravenously to treat rheumatoid arthritis may cause facial flushing, nausea, vomiting and low blood pressure if used with PEARLOC
- dantrolene (infusion for severe body temperature abnormalities), rifampicin, erythromycin, clarithromycin (antibiotics), verapamil, diltiazem (heart medicines), St John's Wort (*Hypericum perforatum*), anti-fungal medicines (e.g. ketoconazole, itraconazole) may affect the way PEARLOC works
- the effects of simvastatin (a medicine to reduce blood cholesterol levels) may be affected by PEARLOC
- baclofen used to treat muscle stiffness in diseases such as multiple sclerosis. may lower your blood pressure further if used with PEARLOC
- other blood pressure lowering medicines, including nitroglycerin, other nitrates and diuretics (water tablets) may increase the antihypertensive effects of PEARLOC

- 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 PEARLOC
- alpha-blockers used for the treatment of enlarged prostate such as prazosin, alfuzosin, doxazosin, tamsulosin, terazosin
- amifostine (used to prevent or reduce side effects caused by other medicines or radiation therapy that are used to treat cancer)
- medicines used to treat mental illnesses such as depression, anxiety, schizophrenia (tricyclic antidepressants, antipsychotics) may lower your blood pressure further when taken with PEARLOC.
- medicines, which are most often used to treat diarrhoea (racecadotril) belonging to the class of so-called mTor inhibitors.

PEARLOC with food and drink

Drinking grapefruit juice with PEARLOC may increase the effects of PEARLOC and lead to very low blood pressure (see Do not take PEARLOC).

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 PEARLOC.

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

Your doctor will normally stop your treatment with PEARLOC and change you to another medicine.

Driving and using machines

Caution is advised as amlodipine (one of the active ingredients of PEARLOC) can have minor or moderate influence the ability to drive and use machines.

PEARLOC does not affect alertness but you might experience dizziness or weakness due to low blood pressure which could affect your ability to drive or operate machinery.

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

PEARLOC contains sodium

PEARLOC contains less than 1 mmol sodium (0,023 g) per tablet, that is to say essentially 'sodium free'.

3. How to take PEARLOC

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

Always take PEARLOC exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Adults:

The usual dose of PEARLOC is one tablet taken once daily in the morning before a meal.

Swallow the tablet whole, with a glass of water, preferably at the same time each day.

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

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

If you take more PEARLOC 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:

- low blood pressure. If marked low blood pressure occurs, symptoms such as dizziness or faintness, nausea, vomiting, cramps, mental confusion, reduced urine output,and electrolyte imbalances may occur.
- excess fluid may accumulate in your lungs (pulmonary oedema) causing shortness of breath that may develop up to 24 – 48 hours after intake.

If you forget to take PEARLOC

If you forget to take PEARLOC, take your normal dose the next day. Do not take a double dose to make up for forgotten individual doses.

If you stop taking PEARLOC

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

4. Possible side effects

PEARLOC can have side effects.

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

If any of the following happens, stop using PEARLOC 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 PEARLOC. 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 center of your chest (heart attack)
- palpitations (very fast heartbeat)
- drooping face, arm weakness and slurred speech (stroke)
- kidney problems (passing less urine than is normal for you), abnormal kidney function, kidney failure
- jaundice (yellowing of the skin and eyes)
- hepatitis (inflammation of the liver with symptoms such as nausea, mild fever, abdominal pain), abnormal liver function (clay coloured stool, dark urine, itching, loss of appetite)
- Stevens-Johnson syndrome or other serious skin disorder (begins with flu-like symptoms, followed by a painful red or purplish rash that spreads and blisters), toxic epidermal necrolysis (TEN) (serious skin disorder with blistering of the skin)
- pancreatitis (inflammation of the pancreas with symptoms such as stomach pain, increased heart rate and fever).

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:

- dizziness, headache, taste disturbances, loss of taste, pins and needles sensation, sleepiness

- visual disturbances, double vision
- tinnitus (ringing or buzzing in the ears), vertigo (spinning sensation, loss of balance)
- cough, dyspnoea (difficulty breathing)
- flushing (hot flushes)
- abdominal pain, nausea, vomiting, indigestion, diarrhoea, constipation, altered bowel habits
- severe itching of the skin (pruritus), rash
- muscle cramps, ankle swelling
- abnormal physical weakness or lack of energy, swelling of the legs or ankles (oedema), fatigue (extreme tiredness).

Less frequent side effects:

- sneezing/runny nose caused by inflammation of the lining of the nose (rhinitis)
- unusual bruising or easy bleeding, feeling generally tired or lethargic, pale skin, signs of infection such as sore throat, fever and chills (these may indicate changes or damage to your blood cells)
- mood changes, anxiety, sleep disturbances, depression, mental confusion, tremors
- low blood pressure, vasculitis (inflammation of the blood vessels that causes changes in the blood vessel walls with symptoms including fever, fatigue, weight loss and muscle and joint pain)
- bronchospasm (tightening of the chest, wheezing and shortness of breath), fever, chest pain worsened by deep breathing, shortness of breath, cough, and a general feeling of illness (eosinophilic pneumonia, a rare type of pneumonia)
- dry mouth, gastritis (inflammation of the lining of the stomach), overgrowth of gum tissue around the teeth
- angioedema (painless swelling under the skin), erythema multiforme (a skin rash which often starts with red itchy patches on your face, arms or legs), excessive sweating,

sensitivity to light, aggravation of psoriasis (chronic skin condition that causes itchy or sore patches of thick red skin with silvery scales), pemphigoid (skin rashes and blistering on the legs, arms, and abdomen), alopecia (spot baldness), purpura (red pinpoints on skin), skin discolouration

- muscle cramps, joint pain, back pain
- passing more or less urine than is normal for you, increased urination at night
- impotence, erectile dysfunction (inability to get or maintain an erection), enlarged breasts in men
- general feeling of discomfort, illness, or unease, raised body temperature (fever)
- weight increase, weight decrease
- accidental fall.

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

- Raynaud's phenomenon (an autoimmune disorder causing blood vessels to spasm when exposed to cold, which may lead to discoloration of fingers and/or toes)
- syndrome of inappropriate antidiuretic hormone secretion (SIADH) (a condition where your body produces too much antidiuretic hormone, which is a hormone that helps the kidneys control the amount of water your body loses through the urine) is a rare complication of an ingredient in PEARLOC
- involuntary and uncontrolled movement disorder.

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

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

You can also send an email directly to the company,

pharmacovigilance@pharmadynamics.co.za, to ensure safety of the product.

5. How to store PEARLOC

Store all medicines out of reach of children.

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

Store in the original container and protect from light and moisture.

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 PEARLOC contains

The active substances are perindopril and amlodipine.

PEARLOC 4 mg/5 mg: Each tablet contains perindopril tert-butylamine 4 mg and amlodipine besilate equivalent to amlodipine 5 mg.

PEARLOC 4 mg/10 mg: Each tablet contains perindopril tert-butylamine 4 mg and amlodipine besilate equivalent to amlodipine 10 mg.

PEARLOC 8 mg/5 mg: Each tablet contains perindopril tert-butylamine 8 mg and amlodipine besilate equivalent to amlodipine 5 mg.

PEARLOC 8 mg/10 mg: Each tablet contains perindopril tert-butylamine 8 mg and amlodipine besilate equivalent to amlodipine 10 mg.

The other ingredients are

calcium hydrogen phosphate (anhydrous), cellulose microcrystalline, crospovidone, glycerol dibehenate, magnesium oxide light, magnesium stearate, sodium starch glycolate (type A) and trehalose dihydrate.

What PEARLOC looks like and contents of the pack

PEARLOC 4 mg/5 mg: White to off-white oval, biconvex tablet with 4 I 5 on one side.

PEARLOC 4 mg/10 mg: White to off-white rectangular, biconvex tablet with 4 I 10 on one side.

PEARLOC 8 mg/5 mg: White to off-white triangular, biconvex tablet with 8 I 5 on one side.

PEARLOC 8 mg/10 mg: White to off-white round, biconvex tablet with 8 I 10 on one side.

The tablets are available in aluminium/aluminium blister packs contained in a printed outer carton. Each carton contains 30 tablets.

The tablets are available in high density polyethylene (HDPE) containers, sealed with foil and a polypropylene child resistant cap. Each container contains 30 tablets.

Holder of Certificate of Registration

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