PACKAGE LEAFLET: INFORMATION FOR THE PATIENT
Perindopril 2mg, 4mg & 8mg Tablets
Perindopril Tert-butylamine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or your pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:
1. What Perindopril is and what it is used for
2. What you need to know before you take Perindopril
3. How to take Perindopril
4. Possible side effects
5. How to store Perindopril
6. Contents of the pack and other information

1. What Perindopril is and what it is used for
Perindopril belongs to a group of medicines called ACE Inhibitors. These work by widening the blood vessels. This makes it easier for your heart to pump blood through the body.

Perindopril is used to:
- Treat high blood pressure (hypertension)
- Treat heart failure (a condition where the heart is unable to pump enough blood to meet the body's needs)
- Reduce the risk of cardiac events, such as heart attack, in patients with stable coronary artery disease (a condition where the blood supply to the heart is reduced or blocked) and who have already had a heart attack and/or an operation to improve the blood supply to the heart by widening the vessels that supply it

2. What you need to know before you take Perindopril
Do not take Perindopril
- If you are allergic to Perindopril, ACE Inhibitors or any of the other ingredients of this medicine (see section 6 "Contents of the pack and other information")
- If you have had symptoms such as wheezing, swelling of the face, tongue or throat, intense itching, skin rash, fainting or feeling dizzy
  If you have had these symptoms when you have taken an ACE Inhibitor in the past or at any other time, this may be angioedema (swelling of the deeper layers of the skin caused by a build-up of fluid). If so, do not take Perindopril
- If you are more than 3 months pregnant (it is also better to avoid Perindopril in early pregnancy – see "Pregnancy and breast-feeding" section)
- If you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren
- If you are having dialysis or any other type of blood filtration. Depending on the machine that is used, Perindopril tablets may not be suitable for you
- If you have kidney problems where the blood supply to your kidneys is reduced (renal artery stenosis)
- If you are being treated with sacubitril/valsartan, a medicine for heart failure. Perindopril must not be started earlier than 36 hours after the last dose of sacubitril/valsartan (see "Other medicines and Perindopril" section)

Warnings and precautions
Talk to your doctor before taking Perindopril:
- 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 drugs belonging to the class of so-called mTor inhibitors (used to avoid rejection of transplanted organs)
  - Gliptins (linagliptin, saxagliptin, sitagliptin, vildagliptin), used to treat diabetes
  - Sacubitril (available as fixed-dose combination with valsartan), used to treat long-term heart failure
- If you suffer from narrowing of the main blood vessel leading from the heart (aortic or mitral stenosis) or heart muscle disease (hypertrophic cardiomyopathy) or narrowing of the artery supplying the kidney with blood (renal artery stenosis)
- If you suffer from any other heart problems such as stable coronary artery disease, unstable angina pectoris, ischaemic heart disease (conditions where the blood supply to the heart is reduced or blocked)
- If you suffer from liver problems
- If you have kidney problems or if you are receiving dialysis
- If you suffer from collagen vascular disease (disease of the connective tissue) such as Systematic Lupus Erythematosus (SLE) or scleroderma
- If you have diabetes
- If you are taking potassium-sparing diuretics (e.g. spironolactone, eplerenone, triamterene, or amiloride), potassium−containing supplements or salt substitutes or medicines associated with increases in potassium in the blood e.g. heparin and co-trimoxazole (trimethoprim/sulfamethoxazole) (see “Other medicines and Perindopril” section)
- If you are to undergo anaesthesia and/or major surgery, you should make sure that the anaesthetist is aware you are taking Perindopril as treatment with Perindopril should be discontinued one day prior to the anaesthesia/surgery
- If you are to undergo a non-surgical treatment that removes cholesterol from the blood by a procedure called LDL apheresis
- If you are going to have desensitisation treatment to reduce the effects of an allergy to a bee or wasp sting
- If you have recently suffered from diarrhoea or vomiting or are dehydrated
- If you are of black origin, you may have a higher risk of developing angioedema (swelling of the deeper layers of the skin caused by a build-up of fluid) and this medicine may be less effective in lowering your blood pressure than in non-black patients
- If you are taking any of the following medicines used to treat high blood pressure:
  - An angiotensin II receptor blocker (ARBs) (also known as sartans - for example valsartan, telmisartan, irbesartan), in particular if you have diabetes-related kidney problems
  - Aliskiren

  Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals. See also information under the heading “Do not take Perindopril”
- If you are pregnant, think that you may be pregnant or are planning to have a baby (see “Pregnancy and breast-feeding” section)
- If you suffer from low blood pressure (hypotension)
- If you suffer from cerebrovascular disease (a group of conditions that affect the circulation of blood to the brain)
- If you suffer from blood disorders. You must tell your doctor if you develop any signs of an infection, such as a sore throat or fever
- If you are taking immunosuppressants, medicines used to reduce the body’s immunity when receiving organ transplant (see “Other medicines and Perindopril” section)
- If you are taking allopurinol, a medicine used to treat gout (see “Other medicines and Perindopril” section)
- If you are taking procainamide, a medicine used to treat irregular heartbeats [digitalis/cardiac glycosides] (see “Other medicines and Perindopril” section)
- If you are currently suffering from a cough
- If you suffer from metabolic acidosis (increased level of acid in the blood)
- If you are taking lithium, a medicine used to treat mood disorders [antipsychotic] (see “Other medicines and Perindopril” section)
- If you have a hormonal disorder called Primary Aldosteronism as use of Perindopril is not recommended

Children and adolescents

Perindopril is not recommended for use in children and adolescents up to the age of 18 years.

Other medicines and Perindopril
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including those obtained without a prescription. This includes herbal medicines.

Your doctor may need to change your dose and/or to take other precautions:
If you are taking an angiotensin II receptor blocker (ARB) or aliskiren (see also information under the headings “Do not take Perindopril” and “Warnings and precautions”).

Medicines which **may interact with or be affected** by Perindopril.
In particular, talk to your doctor before taking Perindopril if you are taking:
- Other medicines used to treat high blood pressure (hypertension) and heart failure (angiotensin II receptor antagonists)
- Medicines used to increase frequency of urination (diuretics)
- Potassium-sparing diuretics such as spironolactone, triamterene, eplerenone or amiloride
- Potassium−containing supplements or salt substitutes or medicines associated with increases in potassium in the blood such as heparin and co-trimoxazole (trimethoprim/sulfamethoxazole)
- Medicines used to treat diabetes such as insulin or oral medicines such as linagliptin, saxagliptin, sitagliptin, vildagliptin
- Muscle relaxants such as baclofen
- Lithium, a medicine used to treat mood disorders (antipsychotic)
- Allopurinol, a medicine used to treat gout
- Medicines used to reduce the body’s immunity when receiving organ transplant such as ciclosporin, tacrolimus (immunosupressants)
- Estramustine, a medicine used to treat prostate cancer
- Medicines used to treat infections such as trimethoprim (antibiotic)
- Procainamide, a medicine used to treat irregular heartbeats
- Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), medicines used to treat certain rheumatic disorders such as, aspirin (more than 3g a day)
- Medicines used to treat depression (tricyclic antidepressants)
- Medicines used to treat severe allergic reactions (sympathomimetics)
- Medicines used to treat angina and heart failure such as nitroglycerin, other nitrates and other vasodilators (medicines used to widen the blood vessels)
- Medicines used to dissolve blood clots (thrombolytics)
- Medicines used to treat heart disorders and high blood pressure (beta blockers)
- Injectable gold to treat rheumatoid arthritis such as sodium aurothiomalate
- Medicines, which is most often 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). See section “Warnings and precautions”
- Gliptins (linagliptin, saxagliptin, sitagliptin, vildagliptin), used to treat diabetes. See section “Warnings and precautions”
- Sacubitril/valsartan, medicine used to treat long-term heart failure. Perindopril must not be started earlier than 36 hours after the last dose of sacubitril/valsartan. See section “Warnings and precautions”

Taking Perindopril with food and drink and alcohol
- Drinking alcohol with Perindopril may make you feel dizzy. Check with your doctor whether you can drink alcohol when taking this medicine
- Take Perindopril in the morning, before a meal

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Pregnancy
You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking Perindopril before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead. Perindopril is **not** recommended

during the first 3 months of 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.

Breast-feeding
Tell your doctor if you are breast-feeding or about to start breast-feeding. The use of Perindopril during breast-feeding is not recommended. Alternative treatments which are established as safe for use during breast-feeding are recommended, especially if your baby is newborn or was born prematurely.

Driving and using machines
Your ability to drive or to operate machinery may be impaired and it may be necessary to avoid driving or operating machinery or pursuing any activity in which full attention is required.

Perindopril contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Perindopril 4mg & 8mg contains sunset yellow FCF (E110)
May cause an allergic reactions.

3. How to take Perindopril
Always take Perindopril exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.
- These tablets are to be taken orally
- The score line on the 4mg tablet is only to facilitate breaking for ease of swallowing and not to divide the tablet into equal doses
- It is recommended to take Perindopril once daily, in the morning, before a meal

<u>High blood pressure (hypertension):</u>
- The recommended starting dose is 4mg given once daily in the morning
- After a month of treatment, the dose may be increased to 8mg once daily
- A starting dose of 2mg may be necessary if you are at risk of an excessive drop in blood pressure (following the recommended starting dose of 4mg) due to the following:
  - Your blood pressure is very high (severe hypertension)
  - You do not have enough water in your body (dehydration)
  - You have a low level of salt in your blood
  - You have a heart disorder where the heart has difficulty pumping blood around the body (cardiac decompensation)
  - You have high blood pressure due to the blood vessels to the kidneys being narrowed (renovascular hypertension)

Older people with high blood pressure:
- The recommended starting dose is 2mg
- After a month, the dose may be increased to 4mg
- The dose may be increased to 8mg if necessary

Patients being treated with diuretic medicine:
- Treatment with diuretic medicine should be discontinued 2 to 3 days before you start taking Perindopril. This is to prevent a drop in your blood pressure
- If needed, you can start taking your diuretic medicine again after you have started treatment with Perindopril
- If it is not possible to discontinue your treatment with diuretic medicine, the recommended starting dose is 2mg of Perindopril

<u>Heart failure:</u>
- The recommended starting dose is 2mg taken in the morning
- This dose may be increased after 2 weeks to 4mg once daily

Stable coronary artery disease:

The recommended starting dose is 4mg once daily for two weeks, then increased to 8mg once daily

Older people with stable coronary artery disease:
The recommended starting dose is 2mg once daily for one week, then 4mg once daily the next week, before increasing the dose up to 8mg once daily

Patients with kidney disorders:
Dosage adjustment may be necessary.

Use in children
Perindopril are not recommended for use in children.

If you take more Perindopril than you should:
If you accidentally take too many tablets, contact your doctor or nearest hospital emergency department **immediately** for advice. Remember to take this leaflet or any remaining tablets with you. **Symptoms of overdose include**: low blood pressure, circulatory shock, kidney failure, faster/deeper breathing than normal, faster/slower heartbeat, irregular heartbeat (palpitations), dizziness, anxiety, cough.

If you forget to take Perindopril
Take it as soon as you remember, unless it is nearly time for your next dose. Do **not** take a double dose to make up for a forgotten dose.

If you stop taking Perindopril
It is important that you keep taking Perindopril for as long as your doctor has told you to.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects
Like all medicines, Perindopril can cause side effects, although not everybody gets them.

Seek medical advice immediately if you develop the following symptoms:
- Allergic reactions: swelling of the face, throat or tongue, difficulty in breathing, dizziness
- Blistering of the skin (pemphigoid)
- Swelling of the face, arms and/or legs, lips, tongue or throat caused by a build-up of fluid (angioedema, peripheral oedema)
- Fever, general ill feeling, itching, joint aches, multiple skin lesions (erythema multiforme)

Common side effects (may affect up to 1 in 10 people)
- Headache
- Dizziness
- A sensation of whirling and loss of balance, feeling dizzy or giddy (vertigo)
- Tingling or numbness in the hands or feet (paraesthesia)
- Visual disturbances
- Ringing in the ears (tinnitus)
- Low blood pressure (hypotension)
- Cough
- Shortness of breath (dysponea)
- Feeling (nausea) or being sick (vomiting)
- Stomach pain or indigestion (dyspepsia)
- Abnormal sense of taste (dysgeusia)
- Diarrhoea
- Constipation
- Skin rash
- Severe itching (pruritus)
- Muscle cramps
- General weakness (asthenia)

Uncommon side effects (may affect up to 1 in 100 people)

- Frequent wheezing, breathlessness, abdominal pain, diarrhoea, fever, cough and rashes due to an increase in certain white blood cells (eosinophilia)
- Low blood sugar levels (hypoglycaemia)
- Abnormally high levels of potassium in blood (hyperkalaemia), this is reversible upon stopping treatment with Perindopril
- Abnormally low levels of salt (sodium) in blood (hyponatremia)
- Changes in mood or sleep
- Sleepiness or drowsiness (somnolence)
- Fainting (syncope)
- Feeling your heartbeat (palpitations)
- Faster heartbeat (tachycardia)
- Inflammation of blood vessels (vasculitis)
- Difficulty in breathing or wheezing (bronchospasm)
- Dry mouth
- Abnormal sensitivity of the skin to sunlight (photosensitivity)
- Excessive sweating (hyperhidrosis)
- Skin rashes with the formation of wheals (urticaria)
- Joint pain (arthralgia)
- Muscle pain (myalgia)
- Kidney problems
- Inability to maintain an erection (impotence)
- Chest pain
- Generally feeling unwell (malaise)
- Fever (pyrexia)
- Changes in the blood
- Fall
- Depression

Rare side effects (may affect up to 1 in 1000 people)
- Increase of liver enzymes and/or bilirubin in the blood
- Psoriasis worsening
- Dark urine, feeling sick (nausea) or being sick (vomiting), muscle cramps, confusion and seizures. These may be symptoms of a condition called SIADH (inappropriate antidiuretic hormone secretion)
- Decreased or absent urine output
- Flushing
- Acute renal failure

Very rare side effects (may affect up to 1 in 10,000 people)
- Decrease in iron (haemoglobin) in the blood
- Decrease in volume of red blood cells in blood (haematocrit)
- A reduction in blood platelets, which increases risk of bleeding or bruising (thrombocytopenia) and/or make infections more likely (leucopenia, neutropenia, agranulocytosis, pancytopenia)
- Reduction in red blood cells which can make the skin pale yellow and cause weakness or breathlessness (haemolytic anaemia)
- Confusion
- Irregular heartbeat (arrhythmia), chest pain (angina pectoris), heart attack (myocardial infarction) and stroke
- Collective symptoms of cough, fever, difficulty breathing, and sweating at night (eosinophilic pneumonia)
- Runny nose (rhinitis)
- Inflammation of the pancreas (pancreatitis)
- Inflammation of the liver (hepatitis)

Frequency not known (cannot be estimated from available data)
- Discoloration, numbness and pain in fingers or toes (Raynaud’s phenomenon)

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Perindopril
- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date, which is stated on the carton after “EXP”. The expiry date refers to the last day of that month.
- Do not store above 25°C.
- Store in the original package in order to protect from moisture.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information
What Perindopril contains:
The active substance is Perindopril tert-butylamine.
- Each 2mg tablet contains 2mg of Perindopril tert-butylamine salt which is equivalent to 1.669mg of Perindopril base
- Each 4mg tablet contains 4mg of Perindopril tert-butylamine salt which is equivalent to 3.338mg of Perindopril base
- Each 8mg tablet contains 8mg of Perindopril tert-butylamine salt which is equivalent to 6.676mg of Perindopril base

The other ingredients are: Lactose monohydrate, Magnesium stearate, Microcrystalline cellulose, Silicon dioxide. 4 mg and 8 mg also contains: D&C Yellow #10 Aluminum Lake, Brilliant Blue FCF Aluminum Lake (E133), Sunset Yellow FCF Aluminum Lake (E110), Microcrystalline cellulose (E460(i)).

What Perindopril Tablets look like and contents of the pack:
- Perindopril 2mg are white, round, biconvex tablets of diameter 5.00mm, engraved with "P" on one face and "2" on the other face
- Perindopril 4mg are light green, capsule-shaped, biconvex, scored tablets of length 8.00mm and breadth 4.00mm, engraved with "P" on both sides of the score line on one face and engraved with "4" on one side of the score line on the other face
- Perindopril 8mg are green, round, biconvex tablets of diameter 8.00mm, engraved with "PP" on one face and "8" on the other face

Perindopril Tablets are available in:
Blister packs of 14, 20, 28, 30, 56 or 60 tablets.

Not all pack sizes may be marketed.

Product Licence Numbers:
- Perindopril 2mg Tablets: PL 11311/0446
- Perindopril 4mg Tablets: PL 11311/0447
- Perindopril 8mg Tablets: PL 11311/0448

Marketing Authorisation Holder and Manufacturer:
Tillomed Laboratories Ltd
220 Butterfield
Great Marlings
Luton
LU2 8DL
UK

This leaflet was last revised in July 2024

Till−Ver.14.1