

Package Leaflet: Information for the user
Perindopril 2mg Tablets
Perindopril 4mg Tablets
Perindopril 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, pharmacist or nurse.
- 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, pharmacist or nurse. 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 Tablets
3. How to take Perindopril Tablets
4. Possible side effects.
5. How to store Perindopril Tablets
6. Contents of the pack and other information

1. What Perindopril is and what it is used for

Perindopril is an angiotensin converting enzyme (ACE) inhibitor. These work by widening the blood vessels, which makes it easier for your heart to pump blood through them.

Perindopril 2 mg or 4 mg tablets are 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.

Perindopril 8 mg tablets are used to:

- treat high blood pressure (hypertension)
- 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 Tablets

Do not take Perindopril

- If you are allergic (hypersensitive) to perindopril or to any of the other ingredients of this medicine (listed in Section 6), or to any other ACE inhibitor,
- If you have experienced symptoms such as wheezing, swelling of the face, tongue or throat, intense itching or severe skin rashes with previous ACE inhibitor treatment or if you or a member of your family have had these symptoms in any other circumstances (a condition called angioedema),
- If you are more than 3 months pregnant. (It is also better to avoid Perindopril in early pregnancy – see pregnancy 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 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 have taken or are currently taking sacubitril/valsartan, a medicine used to treat a type of long-term (chronic) heart failure in adults, the risk of angioedema (rapid swelling under the skin in an area such as the throat) is increased.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Perindopril if:

- you have aortic stenosis (narrowing of the main blood vessel leading from the heart) or hypertrophic cardiomyopathy (heart muscle disease) or renal artery stenosis (narrowing of the artery supplying the kidney with blood)
- you have any other heart problems
- you have liver problems
- you have kidney problems, or if you are receiving dialysis
- you have abnormally increased levels of a hormone called aldosterone in your blood (primary aldosteronism).
- you suffer from a collagen vascular disease (disease of the connective tissue) such as systemic lupus erythematosus or scleroderma
- you have diabetes
- you are on a salt restricted diet or use salt substitutes which contain potassium,
- you are to undergo anaesthesia and/or major surgery,
- are to undergo LDL apheresis (which is removal of cholesterol from your blood by a machine),
- you are going to have desensitization treatment to reduce the effects of an allergy to bee or wasp stings
- you have recently suffered from diarrhoea or vomiting, or are dehydrated
- you have been told by your doctor that you have an intolerance to some sugars.
- 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”.

- you are of black origin since you may have a higher risk of angioedema and this medicine may be less effective in lowering your blood pressure than in non-black patients.
- you are taking any of the following medicines, the risk of angioedema may be increased:
 - racecadotril (a medicine used to treat diarrhea)
 - Medicines used to prevent organ transplant rejection and for cancer (e.g. sirolimus, everolimus, temsirolimus)
 - Vildagliptin, a medicine used to treat diabetes
 - sacubitril (available as fixed-dose combination with valsartan), used to treat long-term heart failure.

Angioedema

Angioedema (a severe allergic reaction with swelling of the face, lips, tongue or throat with difficulty in swallowing or breathing) has been reported in patients treated with ACE inhibitors, including Perindopril. This may occur at any time during treatment. If you develop such symptoms, you should stop taking Perindopril and see a doctor immediately. See also section 4.

You must tell your doctor if you think you are (or might become) pregnant. Perindopril is not recommended in early pregnancy, and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if used at that stage (see pregnancy section).

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.

Treatment with Perindopril can be affected by other medicines. Your doctor may need to change your dose and/or to take other precautions. These include:

- other medicines for high blood pressure, including angiotensin II receptor blockers (ARB), aliskiren (see also information under the headings “Do not take Perindopril” and “Warnings and precautions”) or diuretics (medicines which increase the amount of urine produced by the kidneys)

- potassium supplements (including salt substitutes), potassium-sparing diuretics and other medicines that can increase the amount of potassium in your blood (e.g. trimethoprim and co-trimoxazole for infections caused by bacteria; ciclosporin, an immunosuppressant medicine used to prevent organ transplant rejection; and heparin, a medicine used to thin blood to prevent clots).
- non-steroidal anti-inflammatory drugs (e.g. ibuprofen) for pain relief or high dose aspirin,
- medicines to treat diabetes (such as insulin or metformin)
- baclofen (used to treat muscle stiffness in diseases such as multiple sclerosis) ,
- medicines to treat mental disorders such as depression, anxiety, schizophrenia etc (e.g. tricyclic antidepressants, antipsychotics),
- lithium for mania or depression
- allopurinol for treatment of gout
- immunosuppressants (medicines which reduce the defence mechanism of the body) used to treat auto-immune disorders or following transplant surgery (e.g. ciclosporin, tacrolimus).
- trimethoprim (for the treatment of infections)
- estramustine (used in cancer therapy)
- procainamide (for treatment of irregular heartbeat)
- medicines for the treatment of low blood pressure, shock or asthma (including ephedrine, noradrenaline or adrenaline)
- vasodilators including nitrates (products that make the blood vessels become wider).
- gold salts, especially with intravenous administration (used to treat symptoms of rheumatoid arthritis)
- medicines which are most often used to treat diarrhea (racecadotril)
- medicines which are most often used to avoid rejection of transplanted organs (sirolimus, everolimus and other medicines belonging to the class of mTOR inhibitors). See sections “Do not take Perindopril” and “Warnings and precautions”.
- sacubitril/valsartan (used to treat long-term heart failure). See sections “Do not take Perindopril” and “Warnings and precautions”)

Perindopril with food and drink

It is recommended to take Perindopril tablets in the morning before a meal

Pregnancy and breastfeeding:

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist 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 of Perindopril. Perindopril is not recommended 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.

Breastfeeding:

Tell your doctor if you are breast-feeding or about to start breast-feeding. Perindopril is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby is newborn, or was born prematurely.

Driving and using machines:

Perindopril Tablets usually does not affect alertness but dizziness or weakness due to low blood pressure may occur in certain patients. If you are affected in this way, your ability to drive or operate machinery may be impaired.

Perindopril tablets contain lactose

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

3. How to take Perindopril Tablets

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure..

Swallow your tablet(s) with a glass of water, preferably at the same time each day, in the morning before a meal. Your doctor will decide on the correct dose for you.

The recommended dosages are as follows:

High blood pressure:

The usual starting and maintenance dose is 4 mg once daily.

After one month, this can be increased to 8 mg once a day if required. 8 mg a day is the maximum recommended dose for high blood pressure.

If you are 65 or older, the usual starting dose is 2mg once a day. After a month this can be increased to 4 mg once a day and then if necessary to 8mg once daily

Heart failure: the usual starting dose is 2 mg once daily. After two weeks, this can be increased to 4 mg once a day, which is the maximum recommended dose for heart failure.

Stable coronary artery disease: the usual starting dose is 4 mg once daily. After two weeks, this can be increased to 8 mg once daily, which is the maximum recommended dose in this indication.

If you are 65 or older, the usual starting dose is 2 mg once a day. After a week, this can be increased to 4 mg once a day and after a further week to 8mg once.

Use in children and adolescents

Use in children and adolescents is not recommended.

If you take more perindopril than you should

If you take too many tablets, contact your nearest accident and emergency department if you have taken too high a dose.

The most likely effect in case of overdose is low blood pressure which can make you feel dizzy or faint. If this happens, lying down with the legs raised can help.

If you forget to take perindopril

It is important to take your medicine every day as regular treatment works better. However, if you forget to take a dose of Perindopril, take the next dose at the usual time.

Do not take a double dose to make up for a forgotten dose.

If you stop taking perindopril

Do not stop taking Perindopril 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. Discuss with your doctor before stopping this medicinal product.

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

4. Possible Side Effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking the medicinal product and see a doctor immediately, if you experience any of the following side effects that can be serious:

- swelling of the face, lips, mouth, tongue or throat, difficulty in breathing (angioedema) (See section 2 "Warnings and precautions") (Uncommon - may affect up to 1 in 100 people),
- severe dizziness or fainting due to low blood pressure (Common - may affect up to 1 in 10 people),
- unusual fast or irregular heart beat, chest pain (angina) or heart attack (Very rare - may affect up to 1 in 10,000 people),
- weakness of arms or legs, or problems speaking which could be sign of a possible stroke (Very rare - may affect up to 1 in 10,000 people),
- sudden wheeziness, chest pain, shortness of breath, or difficulty in breathing (bronchospasm) (Uncommon - may affect up to 1 in 100 people)
- inflamed pancreas which may cause severe abdominal and back pain accompanied with feeling very unwell (Very rare - may affect up to 1 in 10,000 people),
- yellowing of the skin or eyes (jaundice) which could be a sign of hepatitis (Very rare - may affect up to 1 in 10,000 people),
- skin rash which often starts with red itchy patches on your face, arms or legs (erythema multiforme) (Very rare - may affect up to 1 in 10,000 people).

Tell your doctor if you notice any of the following side effects:

Common (may affect up to 1 in 10 people)

- headache,
- dizziness,
- vertigo,
- pins and needles,
- vision disturbances,
- tinnitus (sensation of noises in the ears),
- cough,
- shortness of breath (dyspnoea),
- gastrointestinal disorders (nausea, vomiting, abdominal pain, taste disturbances, dyspepsia or difficulty of digestion, diarrhoea, constipation),
- allergic reactions (such as skin rashes, itching),
- muscle cramps,
- feeling of weakness,
- hypotension.

Uncommon (may affect up to 1 in 100 people)

- mood swings,
- sleep disturbances,
- dry mouth,
- intense itching or severe skin rashes,
- formation of blister clusters over the skin (pemphigoid),
- kidney problems,
- impotence,
- sweating,
- excess of eosinophils (a type of white blood cells),
- somnolence,
- fainting,
- palpitations,
- tachycardia,
- vasculitis (inflammation of blood vessels),
- photosensitivity reaction (increased sensitivity of the skin to sun),
- arthralgia (joint pain),
- myalgia (muscle pain),
- chest pain,
- malaise,
- oedema peripheral,
- fever,
- fall,
- change in laboratory parameters: high blood level of potassium reversible on discontinuation, low level of sodium, hypoglycaemia (very low blood sugar level) in case of diabetic patients, increased blood urea, and increased blood creatinine.
- depression

Rare (may affect up to 1 in 1000 people)

- changes in laboratory parameters: Increased level of liver enzymes, high level of serum bilirubin.
- 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 (may affect up to 1 in 10,000 people)

- confusion,
- eosinophilic pneumonia (a rare type of pneumonia),
- rhinitis (blocked up or runny nose),
- changes in blood values such as a lower number of white and red blood cells, lower haemoglobin, lower number of blood platelets.
- haemolytic anaemia in patients with a congenital deficiency of G-6PDH

If you have these symptoms contact your doctor as soon as possible

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 Yellow Card Scheme (Website: www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in 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 Tablets

- Keep this medicine out of the sight and reach of children.
- Do not store above 30°C.
- Do not use this medicine after the expiry date which appears on the packet after "do not use after" or "exp". The first 2 figures show the month, while the last figures show the year. The expiry date refers to the last day of that month.
- Do not use this medicine if you notice any discolouration of the tablets.
- 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 to protect the environment.

6. Contents of the pack and other information

What Perindopril Tablets contains

The active substance is:

Perindopril tert-butylamine.

Each Perindopril 2 mg tablet contains 2 mg of perindopril tert-butylamine salt equivalent to 1.669mg of perindopril.

Each Perindopril 4 mg tablet contains 4 mg of perindopril tert-butylamine salt equivalent to 3.338mg of perindopril.

Each Perindopril 8 mg tablet contains 8 mg of perindopril tert-butylamine salt equivalent to 6.676mg perindopril.

Other ingredients (excipients) are:

Hydrophobic colloidal silica, microcrystalline cellulose, lactose and magnesium stearate.

What Perindopril Tablets looks like and contents of the pack

2 mg:

White, round, biconvex tablets, plain on both sides. Tablet dimension: 5.00 mm

4 mg:

White, oblong tablets with a score line on both sides, 'PP' on one side and '4' on the other. The tablets can be divided into equal halves. Tablet dimensions: 8.00 mm x 4.00 mm

8 mg:

White, round, biconvex tablets with 'PP' on one side and '8' on the other. Tablet dimension: 8.00 mm

Each strength of tablet is available in packaging containing 14, 20, 28, 30, 56, 60, 90 and 100 tablets in alu-alu blister packaging.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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