



PACKAGE LEAFLET: INFORMATION FOR THE USER

PERINDOPRIL 2MG, 4MG AND 8MG FILM-COATED TABLETS (perindopril tert-butylamine)

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Perindopril Tablets are and what they are used for
2. Before you take Perindopril Tablets
3. How to take Perindopril Tablets
4. Possible side effects
5. How to store Perindopril Tablets
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The information in this leaflet refers to Perindopril Film-coated Tablets available in 2mg, 4mg and 8mg strengths.

1. WHAT PERINDOPRIL TABLETS ARE AND WHAT THEY ARE USED FOR

Perindopril belongs to a class of medicines called ACE inhibitors. These work by widening the blood vessels making it easier for your heart to pump blood through them.

Perindopril Tablets are used:

- to treat high blood pressure (hypertension)
- to treat heart failure (a condition where the heart is unable to pump enough blood to meet the body's needs)
- to reduce the risk of cardiac events 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. BEFORE YOU TAKE PERINDOPRIL TABLETS

Do not take Perindopril Tablets:

- If you are allergic (hypersensitive) to perindopril or any other ACE inhibitor, or to any of the other ingredients in the tablets (see section 6 for a list of ingredients)
 - If you have had symptoms such as wheezing, swelling of the face, tongue or throat, intense itching, skin rashes, fainting or dizziness with previous ACE inhibitor treatment or have these symptoms in other circumstances (this is 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).
 - Perindopril Tablets should not be given to children
- If you think any of the above situations applies to you, do not take the tablets. Consult your doctor and take his/her advice.

Take special care with Perindopril Tablets

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)

You should check with your doctor BEFORE taking Perindopril Tablets:

- If you have aortic stenosis (narrowing of the main blood vessel leading from the heart) or hypertrophic cardiomyopathy (cardiac muscle disease) or renal artery stenosis (narrowing of the artery supplying the kidney with blood)
- If you have any other heart or liver or kidney problems, or if you are receiving dialysis
- If you suffer from a collagen disease such as systemic lupus erythematosus of scleroderma
- If you are on a salt restricted diet or use salt substitutes which contain potassium

- If you suffer from diabetes which is not well controlled

You should also inform your doctor or the medical staff that you are taking Perindopril Tablets:

- If you undergo anaesthesia and/or surgery
- If you have suffered from recent diarrhoea or vomiting
- 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 L.D.L. apheresis (which is removal of cholesterol from your blood by a machine)

Taking other medicines

In order to avoid possible interactions between different medicines, please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Tell your doctor if you are taking any of the following to be sure that it is safe to take Perindopril at the same time:

- Other medicines for treating high blood pressure including diuretics (water tablets)
 - Potassium-sparing diuretics (eg spironolactone, triamterene, or amiloride); potassium supplements and potassium containing salt substitutes
 - Medicines for the treatment of diabetes (insulin) or tablets to lower blood sugar
 - Lithium for mania or depression
 - Medicines for the treatment of mental disorders such as depression, anxiety, schizophrenia or other psychoses
 - Allopurinol used for the treatment of gout
 - Immunosuppressants used for the treatment of auto-immune disorders (eg rheumatoid arthritis) or following transplant surgery
 - Procainamide, a treatment for irregular heartbeat
 - Non-steroidal anti-inflammatory drugs (NSAIDs) for pain relief, including aspirin
 - Medicines used for the treatment of low blood pressure, shock or asthma (eg ephedrine, noradrenaline or adrenaline)
 - Vasodilators including nitrates (products that make the blood vessels become wider)
 - Heparin (used to thin the blood)
- Ask your doctor if you are not sure what these medicines are.

Taking Perindopril Tablets with food and drink

It is recommended that you take Perindopril Tablets before a meal. This helps reduce the effect of food on the way in which the medicine works. Drinking alcohol with Perindopril Tablets may make you feel dizzy or light-headed. You should check with your doctor whether drinking is advisable for you.

Pregnancy and breast feeding

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 breastfeeding 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

You may experience dizziness or weariness while taking Perindopril. If this occurs do not drive or use machinery. You should talk to your doctor.

3. HOW TO TAKE PERINDOPRIL TABLETS

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





Your doctor will decide on the right starting dose for you and any increase in the dose, depending on your condition, and whether you are taking any other medicines. Do not change your dose unless your doctor tells you to. Perindopril Tablets may be used on their own or with other medicines which lower blood pressure.

How to take your tablets:

Take your tablet(s) with a glass of water in the morning, preferably at the same time each day before a meal. If you are taking water tablets (diuretics), your doctor may decide to reduce or even discontinue these at the beginning of your treatment with Perindopril Tablets.

The usual doses of Perindopril Tablets are as follows:

High blood pressure

Adults: the usual starting and maintenance dose for treatment is 4 mg once a day. After a month, this can be increased to 8 mg a day (the maximum recommended dose).
Elderly (65 years or over): the usual starting dose is 2 mg once a day. After a month, this can be increased to 4 mg a day and if necessary to 8mg a day.

Heart failure

Adults, including the elderly: treatment should be started under close medical supervision with 2 mg once a day. After 2 weeks it can be increased to 4 mg once a day if required.

Stable coronary artery disease

Adults: the usual starting dose is 4 mg once daily. After 2 weeks and if 4 mg is well tolerated, this can be increased to 8 mg once daily.
Elderly (65 years or over): the usual starting dose is 2 mg once daily. After one week, this can be increased to 4 mg once daily and after a further week to 8 mg once daily.

Your doctor may give you a blood test to check that your kidneys are working properly before increasing the dose to 8 mg.

Treatment for these conditions is usually life-long.

Perindopril is not suitable for use in children.

If you take more tablets than you should:

If you have taken too many tablets, contact your nearest hospital accident and emergency department or tell your doctor IMMEDIATELY.

If you forget to take your tablets:

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. Do not take a double dose.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Perindopril Tablets can cause side effects, although not everybody gets them. Do not be alarmed by the list below, you may not get any of them.

Stop taking your tablets at once and TELL YOUR DOCTOR IMMEDIATELY if you experience any of the following effects of angioedema:

- swelling of the face, lips, mouth, tongue or throat, difficulty in breathing
- dizziness or fainting
- unusually fast or irregular heartbeat

This is an uncommon but serious reaction which can occur with all drugs of this type (ACE inhibitors). It must be treated immediately, usually in hospital

Common (probably affecting up to 1 in 10 people)

- Cough, shortness of breath
- Light-headedness due to low blood pressure (particularly after the first few doses, if the dose is increased or when water tablets are also taken)
- Headache, dizziness, vertigo, tiredness, pins and needles, muscle cramps, visual disturbances (eg blurred vision, eye pain) tinnitus (sensation of noises in the ears)
- Nausea, vomiting, abdominal pain, changes in your sense of taste, feeling of indigestion, diarrhoea, constipation
- Skin rashes, itching

Uncommon (probably affecting less than 1 in 100 people)

- Changes in mood or sleep

- Bronchospasm (tightening of the chest, wheezing and shortness of breath)
- Dry mouth
- Kidney problems
- Impotence
- Sweating
- Angioedema (see above).

Very rare (probably affecting less than 1 in 10,000 people)

- Confusion
- Irregular heartbeat, angina, heart attack and stroke (these have been reported with ACE inhibitors in association with low blood pressure)
- Eosinophilic pneumonia (a rare type of pneumonia), rhinitis (blocked up or runny nose)
- Pancreatitis (inflammation of the pancreas)
- Hepatitis (inflammation of the liver)
- Erythema multiforme (skin reaction like an allergy)
- Kidney failure

Changes in the blood: your doctor may decide to carry out blood tests at intervals to monitor this.

If you experience any of the above symptoms and they persist or become troublesome, you should tell your doctor. If you notice any other effects not mentioned in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE PERINDOPRIL TABLETS

Store below 25°C.

Store in the original package

Keep out of the reach and sight of children.

Do not use Perindopril Tablets after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Perindopril Tablets contain:

- The active substance is perindopril tert-butylamine. Each tablet contains 2, 4 or 8mg of perindopril tert-butylamine.
- The other ingredients are mannitol, sodium starch glycollate, sodium carbonate anhydrous, hypromellose, macrogol-6000, siliconised talc and magnesium stearate
- The tablet coating contains hypromellose and Opadry white

What Perindopril Tablets look like and contents of the pack

The 2mg tablets are circular, white to off-white, plain on both sides

The 4mg tablets are barrel-shaped, white to off-white, with a break line on both sides and 'PR' and '4' on one side.

The 8mg tablets are barrel-shaped, white to off-white, with a break line on both sides and 'PR' and '8' on one side.

The tablets are packed in blister strips and are available in cartons containing 30 tablets.

This medicinal product is authorised in the Member States of the EEA under the following names:

Perindopril 2mg Film-coated Tablets, Perindopril 4mg Film-coated Tablets and Perindopril 8mg Film-coated Tablets.

Marketing Authorisation Holder:

Strandhaven Ltd trading as Somex Pharma, Seven Kings, Ilford, Essex, IG3 8BS, UK

Manufacturer:

Strandhaven Ltd trading as Somex Pharma, Seven Kings, Ilford, Essex, IG3 8RA, UK

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