

Pendrex 8 mg Tablets

perindopril tert-butylamine

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please 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 gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or your pharmacist.

In this leaflet

- 1. What Pendrex is and what it is used for
- 2. Before you take Pendrex
- 3. How to take Pendrex
- 4. Possible side effects
- 5. How to store Pendrex
- 6. Further information



1 What Pendrex is and what it is used for

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

Pendrex tablets are used:

- to treat high blood pressure (hypertension)
- to 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 Before you take Pendrex

Do not take Pendrex

- if you are **allergic (hypersensitive)** to Perindopril or any of the other ingredients in the tablet **or any other ACE inhibitor** (see section 6)
- 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 had these symptoms in any other circumstances (this is a condition called angioedema)
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren
- if you have hereditary tendency to **tissue swelling** or tissue swelling of unknown origin (hereditary or idiopathic angioedema)
- if you are more than 3 months pregnant (it is also better to avoid Pendrex in early pregnancy – see pregnancy section).

If you think any of the above situations apply to you do not take the tablets. Consult your doctor and take his/her advice.

Warnings and precautions

Talk to your doctor **before** taking Pendrex:

- if you are at **risk of an excessive fall in the blood pressure**. This may be the case, among others, if you suffer from heart failure, impaired renal function or disorders in the salt and fluid balance, e.g. because you take diuretics (medicines that increase urine production) or keep low-salt diet or as a consequence of vomiting or diarrhoea
- if you have aortic stenosis (**narrowing of the main blood vessel leading from the heart**), mitral valve stenosis (**narrowing of heart’s mitral valve**), hypertrophic cardiomyopathy (**cardiac muscle disease**) or renal artery stenosis (**narrowing of the artery supplying the kidney with blood**)
- if you have hypersensitivity reactions or tissue swelling (angioedema) during treatment with perindopril or other ACE inhibitors. Angioneurotic oedema more frequently occur in patients with black skin colour than in patients with non-black skin colour.
- if you have a **heart problem**
- if you have a **liver problem**
- if you have a **kidney problem**
- if you are **receiving dialysis**
- if you suffer from a **collagen disease** such as systemic lupus erythematosus or scleroderma
- if you are on a **salt restricted** diet or use **salt substitutes which contain potassium**
- if you suffer from a **diabetes which is not well controlled**
- 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 Pendrex”.
- 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)
- if you are **breast-feeding**.

You must tell your doctor if you think you are (or might become) pregnant. Pendrex 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).

Perindopril tablets are **not recommended** for **children**.

You should also inform your doctor or medical staff that you are taking Pendrex:

- if you had an episode of **chest pains** (angina pectoris)
- if you are to **undergo anaesthesia** and/or **surgery**
- if you have suffered from recent **diarrhoea** or **vomiting**
- if you are going to have **desensitization treatment** to reduce the effects of an allergy to bee or wasp stings
- if you are to **undergo LDL apheresis** (which is removal of cholesterol from your blood by a machine)
- if your **blood pressure is not sufficiently lowered** due to your ethnic affiliation (particularly in patients with black skin colour)
- if you have **persistent dry cough**.

Other medicines and Pendrex

Tell your doctor or pharmacist, if you are taking, have recently taken or might take any other medicines. In particular, you should check with your doctor if you are taking any of the following to be sure that it is safe to take Perindopril:

- other medicines for **treating high blood pressure** including diuretics (**water tablets**)
- **potassium-sparing diuretics** (e.g. 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 **treatment of 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** (e.g. rheumatoid arthritis) or **following transplant surgery**
- procainamide, a **treatment for irregular heartbeat**
- non-steroidal anti-inflammatory drugs (NSAIDs) **medications for pain relief**, including aspirin (if dose is higher or equal to 3g/day)
- medicines used for the treatment of **low blood pressure, shock** or **asthma** (e.g. ephedrine, noradrenaline or adrenaline)
- vasodilators including nitrates (**product that make the blood vessels become wider**)
- heparin (blood **thinning medication**)
- gold (sodium aurothiomalate), for the **treatment of arthritis**
- medicines which are 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”.

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 Pendrex” and “Warnings and precautions”).

Ask your doctor if you are not sure what these medicines are.

Tell your doctor or dentist **before** having an **anaesthetic** or **surgery**, because your blood pressure may fall suddenly during the anaesthesia.

Taking Pendrex with food and drink

It is recommended that Pendrex should be taken before a meal with sufficient amount of fluid (e.g. water) in order to reduce the influence of food on the way in which the medicine works.
Potassium containing food additives or salt substitutes should not be used if you use Pendrex. The blood potassium concentration can be elevated too high. Also large amounts of (plain) salt (NaCl) in the diet may reduce the antihypertensive effect of Pendrex.

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 Pendrex before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Pendrex. Pendrex 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.

Breast-feeding

Tell your doctor if you are breast-feeding or about to start breast-feeding. Pendrex 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.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

No studies on the effects on the ability to drive and use machines have been performed.
However, Pendrex does not affect alertness but different reactions such as dizziness or weakness in relation to the decrease in blood pressure may occur in certain patients, especially in the beginning of treatment or when increasing the dose. If affected, your ability to drive or to operate machinery may be impaired.

3 How to take Pendrex

Always take this medicine exactly as your doctor told you. Please ask your doctor or pharmacist if you are not sure.
Pendrex may be used on its own or with other medicines which lower blood pressure.

The usual dosages for Pendrex are as follows:
High blood pressure: the usual starting and maintenance dose for treatment in adults is 4 mg once a day. After a month, this can be increased to 8 mg a day which is the maximum recommended dose.

If you are 65 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 8 mg a day.

Stable coronary artery disease: the usual starting dose is 4 mg once daily. After two weeks and if 4 mg is well tolerated, this can be increased to 8 mg once daily. If you are 65 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.
In case of impaired renal function, your doctor will adjust the dose of Pendrex for you.
Treatment of these conditions is usually life-long.
Take your tablet(s) with a glass of water, preferably at the same time each day, in the morning, 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.

Pendrex is not suitable for use in children.

If you take more Pendrex than you should

If you take too many tablets, contact your nearest hospital casualty department or tell your doctor immediately. The most likely effect in case of overdose is low blood pressure. If marked low blood pressure occurs (symptoms such as dizziness or faintness), lying down with the legs raised can help.

If you forget to take Pendrex

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.

Continued on the next page >>

If you stop taking Pendrex

Always consult your doctor, if you wish to stop taking this medicine. Even if you feel well, it may be necessary to continue taking this medicine.

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.

This side effect occurs uncommonly (affecting less than 1 in every 100 people). However, if you notice any of the following side effects, contact your doctor immediately:

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

These are symptoms of a serious reaction (angioedema) which can occur with all other drugs of this type (ACE inhibitors). It must be treated immediately, usually in hospital.

Other possible side effects

Common (affecting less than 1 in every 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 (e.g. 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 (affecting less than 1 in every 100 people):

- changes in mood or sleep
- bronchospasm (tightening of the chest, wheezing and shortness of breath)
- dry mouth
- kidney problems
- impotence
- sweating.

Rare (may affect up to 1 in 1000 people):

- psoriasis worsening.

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

- confusion
- irregular heartbeat, heart attack and stroke (these have been reported with ACE inhibitors in association with low blood pressure)
- angina pectoris (chest tightness)
- 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 disorder resulting from allergic reaction provoked by many different causes)
- changes in the blood cell count: your doctor may decide to carry out blood tests at intervals to monitor for this.

Not known (frequency cannot be estimated from the available data):

- hypoglycaemia (very low blood sugar level)
- vasculitis (inflammation of blood vessels).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Pendrex

Keep out of the reach and sight of children.

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

Do not store above 30°C.

Store in the original package in order to protect from moisture.

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 Pendrex contains:

The active substance is: perindopril tert-butylamine. Each tablet contains 8 mg perindopril tert-butylamine, equivalent to 6.676 mg perindopril.

The other ingredients are: microcrystalline cellulose, silicified microcrystalline cellulose, polacrillin potassium, silicone dioxide, colloidal anhydrous silica, magnesium stearate and hydroxypropylbetadex.

What Pendrex looks like and contents of the pack

Pendrex 8 mg Tablets are white, round, biconvex tablet debossed with 8 on one side.

Aluminium/Aluminium blister.

Pack sizes: 7, 10, 14, 15, 28, 30, 56, 60, 90, 100, 112, 120 tablets

Not all pack sizes may be marketed.

Marketing Authorization Holder and Manufacturers Marketing Authorization Holder

Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers

Lek Pharmaceuticals d.d., Verovškova 57, 1526 Ljubljana, Slovenia.
LEK S.A., ul. Domaniewska 50 C, 02-672 Warszawa, Poland.
Salutas Pharma GmbH, Otto-von-Guericke-Allee 1, 39179 Barleben, Germany.
Salutas Pharma GmbH, Dieselstrasse 5, 70839 Gerlingen, Germany.
Lek Pharmaceuticals d.d., Trimlini 2D, 9220 Lendava, Slovenia.

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

Ireland: Pendrex 8 mg Tablets
Latvia: Perindalon 8 mg tablets
United Kingdom: Perindopril 8 mg Tablets

This leaflet was last approved in 09/2016.

I.M. L/313c 10-16
46191899