Package leaflet: Information for the patient

Pendrex 2 mg Tablets
Pendrex 4 mg Tablets

perindopril erbumine

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, please ask your doctor or 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 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 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, 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 Pendrex

Do not take Pendrex:
- if you are **allergic** to perindopril or any of the other ingredients of this medicine (listed in section 6) **or to any other ACE inhibitor**
- 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 condition called angioedema)
- if you have hereditary tendency to **tissue swelling** or tissue swelling of unknown origin (hereditary or idiopathic angioedema)
- 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, Pendrex 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 more than 3 months pregnant (it is also better to avoid Pendrex in early pregnancy – see pregnancy section)
- 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, as the risk of angioedema (rapid swelling under the skin in an area such as the throat) is increased.

If you think any of the above situations applies 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 in **risk of an excessive fall in 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 any other **heart problems**
- if you have hypersensitivity reactions or tissue swelling (angioedema) during treatment with perindopril or other ACE inhibitors. Angioedema more frequently occur in patients with black skin colour than in patients with non-black skin colour.
- 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 have been diagnosed with a condition called **hypoaldosteronism** (a decreased level of the hormone aldosterone in your blood)
- if you have abnormally increased levels of a hormone called aldosterone in your blood (primary aldosteronism)
- if you are on a **salt restricted** diet or use **salt substitutes which contain potassium**
- if you suffer from a **diabetes**
- 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 (rapid swelling under the skin in area such as the throat) may be increased:
  - racecadotril (a medicine used to treat diarrhoea)
  - medicines used to prevent organ transplant rejection and for cancer (e.g. temsirolimus, sirolimus, everolimus and other medicines belonging to the class of mTOR inhibitors)
  - vildagliptin and other medicines belonging to the class of gliptins (used to treat diabetes).
- 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).

Children and adolescents

Pendrex is **not recommended** for **children** and **adolescents** up to the age of 18 years.

You should also inform your doctor or pharmacist 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**, or are **dehydrated**
- 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 this medicine:

- other medicines for **treating high blood pressure**, including angiotensin II receptor blockers (ARBs), aliskiren or diuretics (**water tablets**)
  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").
- **potassium supplements, potassium-sparing diuretics** (e.g. spironolactone, eplerenone, triamterene or amiloride); other medicines that can increase **the amount of potassium in your blood** (e.g. trimethoprim and heparin and co-trimoxazole also known as trimethoprim/sulfamethoxazole) 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), potassium-sparing medicines used in the treatment of heart failure: eplerenone and spironolactone at doses between 12.5 mg to 50 mg by day
- medicines for the **treatment of diabetes** (insulin or tablets such as vildagliptin) 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), **medicines for pain relief**, including acetylsalicylic acid (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**)
- gold (sodium aurothiomalate), for the **treatment of arthritis**
- a medicine which is most often used to **treat diarrhoea** (racecadotril)
- medicines which are most often used **to avoid rejection of transplanted organs** (sirolimus, everolimus, temsirolimus and other medicines belonging to the class of mTOR inhibitors). See section "Warnings and precautions"
- estramustine (used in **cancer therapy**)
- baclofen (used to treat muscle stiffness in diseases such as **multiple sclerosis**).

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.

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 this 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 affects 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. 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 doses 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.

Heart failure: treatment should be started under close medical supervision with 2 mg once a day. After two weeks, it can be increased to 4 mg a day if required.

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 beginning of your treatment with perindopril.

Use in children and adolescents
Use in children and adolescents up to the age of 18 years is not recommended.

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 to make up for a forgotten dose.

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 medicine, 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 this medicine 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
- dizziness or fainting
- unusually fast or irregular heartbeat.

These are symptoms of a serious reaction (angioedema) which can occur with all other medicines of this type (ACE inhibitors). It must be treated immediately, usually in hospital. They occur uncommonly (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)
- irregular heartbeat, heart attack and stroke (these have been reported with ACE inhibitors in association with low blood pressure), angina pectoris (chest tightness) (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)
- inflammation of the 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)
- skin rash which often starts with red itchy patches on your face, arms or legs disorder resulting from allergic reaction provoked by many different causes (erythema multiforme) (Very rare – may

affect up to 1 in 10,000 people)
- yellowing of the skin or eyes (jaundice) which could be a sign of inflammation of the liver (hepatitis) (Very rare – may affect up to 1 in 10,000 people)
- not going to the toilet (low urine output) which can also occur with a high temperature (fever), nausea, tiredness, pain in your sides, swelling of your legs, ankles, feet, face and hands or blood in your urine. These are due to a severe kidney problem (sudden kidney failure) (Very rare, may affect up to 1 in 10,000 people).

Other possible side effects

Common (may affect 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 (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 (may affect up to 1 in 100 people):
- excess of eosinophils (a type of white blood cells)
- hypoglycaemia (very low blood sugar level), high blood level of potassium reversible on discontinuation, low level of sodium
- changes in mood or sleep
- somnolence, fainting
- palpitations, tachycardia
- vasculitis (inflammation of blood vessels)
- dry mouth
- kidney problems
- impotence
- increased sweating, increased sensitivity of the skin to sun, formation of blister clusters over the skin
- hives
- arthralgia (joint pain), myalgia (muscle pain)
- chest pain, malaise, oedema peripheral, fever
- increased blood urea, and increased blood creatinine
- fall.

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

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 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):
- discolouration, numbness and pain in fingers or toes (Raynaud's phenomenon).

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 the national reporting system: HPRA Pharmacovigilance; website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Pendrex

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 blister and carton after EXP. 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.

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 Pendrex contains
The active substance is perindopril erbumine.

2 mg
Each tablet contains 2 mg of perindopril erbumine, equivalent to 1.669 mg perindopril.

4 mg
Each tablet contains 4 mg of perindopril erbumine, equivalent to 3.338 mg perindopril.

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

What Pendrex looks like and contents of the pack
2 mg:
White, round, biconvex tablets debossed with 2 on one side.

4 mg:
White, round, biconvex tablets scored on one side and debossed with 4 on the reverse side. The tablet can be divided into equal doses.

The tablets are packed in aluminium/aluminium blister which are inserted in a carton folder.
Pack sizes: 7, 10, 14, 15, 20, 28, 30, 50, 56, 60, 90, 100, 112, 120 tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers
Marketing Authorisation 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.

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 2 mg Tablets
	Pendrex 4 mg Tablets
Italy:	Perindopril Almus
Latvia:	Perindalon 4 mg tabletes

This leaflet was last revised in 05/2021.