

Pendrex Plus 4mg/1.25mg Tablets

perindopril erbumine/indapamide

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 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 Plus is and what it is used for
2. What you need to know before you take Pendrex Plus
3. How to take Pendrex Plus
4. Possible side effects
5. How to store Pendrex Plus
6. Contents of the pack and other information

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1 What Pendrex Plus is and what it is used for Pendrex Plus

Pendrex Plus tablets are a combination of two active ingredients, perindopril and indapamide. This medicine is used in the treatment of high blood pressure (hypertension).

- 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.
- Indapamide is a diuretic. Diuretics increase the amount of urine produced by the kidneys and are sometimes called water tablets. However, indapamide is different from other diuretics, as it only causes a slight increase in the amount of urine produced.

Each of the active ingredients reduces blood pressure and they work together to control your blood pressure.

2 What you need to know before you take Pendrex Plus

Do NOT take Pendrex Plus:

- if you are **allergic** to perindopril or any other ACE inhibitor, or indapamide or other sulphonamides or any of other ingredients of this medicine (listed in section 6 and end of section 2)
- if you have experienced symptoms such as **wheezing, swelling of the face or tongue, 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 have a **severe liver disease** or suffer from a condition called **hepatic encephalopathy** (degenerative disease of the brain)
- if you have a **severe kidney disease** or if you are **receiving dialysis**
- if you have **diabetes or impaired kidney function** and you are treated with a blood pressure lowering medicine containing **aliskiren**
- if you have **low or high blood potassium**
- if you are suspected of having untreated **decompensated heart failure** (severe water retention, difficulty in breathing)
- if you are more than **3 months pregnant**. (It is also better to avoid Pendrex Plus in early pregnancy – see pregnancy section.)
- if you are **breast-feeding** (see breast-feeding).

Warnings and precautions

Talk to your doctor **BEFORE** taking Pendrex Plus:

- if you have **narrowing of the main blood vessel** leading from the heart (aortic stenosis)
- if you have **narrowing of heart's left valve** (mitral valve stenosis)
- if you have **cardiac muscle disease** (hypertrophic cardiomyopathy)
- if you have **narrowing of the artery supplying the kidney** with blood (renal artery stenosis)
- if you have any other **heart problems** or problems with **your kidneys**
- if you have **liver problems**
- if you suffer from a **collagen disease** (skin disease) such as systemic lupus erythematosus or scleroderma
- if you have **atherosclerosis** (hardening of the arteries)
- if you suffer from **hyperparathyroidism** (dysfunctioning of the parathyroid gland)
- if you suffer from **gout**
- if you have **diabetes**
- if you are on a **salt restricted diet** or use salt substitutes which contain **potassium**
- if you take **lithium or water tablets** called potassium-sparing diuretics (spironolactone, triamterene) as their use with Pendrex Plus should be avoided (see "Other medicines and Pendrex Plus")
- 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 Plus".

- if you are taking any of the following medicines, the risk of angioedema (rapid swelling under the skin in area such as the throat) is increased:
 - racecadotril (used to treat diarrhoea)
 - sirolimus, everolimus, temsirolimus and other medicines belonging to the class of mTOR inhibitors (used to avoid rejection of transplanted organs)
- if you are more than **70 years old**
- if you think you are (or might become) **pregnant**. Pendrex Plus 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 also inform your doctor or pharmacist that you are taking this medicine if you:

- are to **undergo anaesthesia and/or surgery**
- have recently suffered from **diarrhoea or vomiting**, or are **dehydrated**
- have increased sensitivity of the skin to **sunlight**
- have a persistent **dry cough**
- have **abdominal pain with or without nausea or vomiting**; these may be symptoms of serious allergic reaction called intestinal angioedema
- are to undergo **dialysis** or **LDL aphaeresis** (removal of cholesterol from your blood by a machine)
- are going to have **desensitisation treatment** to reduce the effects of an allergy to bee or wasp stings,
- are to undergo a medical test that requires injection of an **iodinated contrast agent** (a substance that makes organs like kidney or stomach visible on an X-ray).

Pendrex Plus may be less effective in **black people**.

Children and adolescents

Do NOT give this medicine to children and adolescents.

Other medicines and Pendrex Plus

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Avoid taking this medicine with:

- **lithium** (used to treat depression)
- **water tablets** (potassium-sparing diuretics such as spironolactone, triamterene)
- **potassium salts**
- other medicines which can increase potassium in your body (such as heparin and co-trimoxazole also known as trimethoprim/sulfamethoxazole).

In particular, **before taking** this medicine check with your doctor if you are taking any of the following:

- other medicines for treating **high blood pressure** 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 Plus" and "Warnings and precautions").
- medicines used for **heart rhythm problems** (e.g. procainamide, digoxin, hydroquinidine, disopyramide, quinidine, amiodarone, sotalol, diphemanil)
- **antihistamines** for hay fever or allergies e.g. terfenadine, astemizole, mizolastine
- **bepridil** (for angina pectoris)
- **benzamides** (for psychotic disorders e.g. sultopride)
- **butyrophenones** (for psychotic disorders e.g. haloperidol)
- **cisapride** (intestinal medicine)
- **erythromycin** by injection (an antibiotic)
- **moxifloxacin** or **sparfloxacin** (antibiotics)
- **methadone** (anti-addiction medicine)
- **allopurinol** (for gout)
- **corticosteroids** used to treat various conditions including severe asthma and rheumatoid arthritis
- **immunosuppressants** used for the treatment of autoimmune disorders or following transplant surgery (e.g. ciclosporin)
- medicines for treating **cancer**
- **halofantrine** (for malaria)
- **pentamidine** (for pneumonia)
- **vincamine** (for symptomatic cognitive disorders in elderly)
- **baclofen** (for muscle stiffness occurring in diseases such as multiple sclerosis)
- **diabetes medicines** such as insulin, metformin or glimepiride
- **calcium**
- **stimulant laxatives** (e.g. senna)
- non-steroidal anti-inflammatory drugs (NSAIDs) for **pain relief** or high dose salicylates (e.g. **acetylsalicylic acid**)
- **amphotericin B** by injection (for severe fungal disease)
- medicines to treat mental disorders such as depression, anxiety, schizophrenia (e.g. **tricyclic antidepressants, neuroleptics**)
- **tetracosactide** (to treat Crohn's disease)
- **gold** (sodium aurothiomalate) by injection (medicine for rheumatic disorders)
- medicines, which is most often used to treat diarrhoea (**racecadotril**) or avoid rejection of transplanted organs (**sirolimus, everolimus, temsirolimus and other medicines belonging to the class of mTOR inhibitors**). See section "Warnings and precautions".

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

Pendrex Plus with food and drink

Take special care if you are on a salt-restricted diet. See your doctor before you take this medicine.

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

You must not take Pendrex Plus if you are breast-feeding.

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

Driving and using machines

This medicine does not affect your alertness but you may feel dizzy or weak due to a decrease in your blood pressure, especially at the beginning of treatment or when increasing the dose. If this happens, your ability to drive or to operate machinery may be affected.

Pendrex Plus 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.

3 How to take Pendrex Plus

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

Take your tablet with a glass of water preferably in the morning and before a meal.

Adults

The recommended dose is one tablet once a day.

Elderly

Your doctor will decide on the best dose for you.

Patients with kidney insufficiency

Your doctor may decide to modify the dosage regimen if you suffer from kidney impairment.

continued on the next page»

Use in children and adolescents

This medicine should not be given to children and adolescents (see "Warnings and precautions").

If you take more Pendrex Plus than you should

If you take too many tablets, contact your nearest hospital 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 your legs raised can help.

If you forget to take Pendrex Plus

It is important to take your medicine every day as regular treatment is more effective. 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 one.

If you stop taking Pendrex Plus

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.

If you notice any of the following side effects, STOP taking the tablets and contact your doctor immediately. These are symptoms of a serious **allergic reaction** and must be treated **immediately**, usually in a **hospital**.

- swelling of the face, lips, mouth, tongue, eyes or throat
- difficulty in breathing
- severe dizziness or fainting
- blistering of the skin, mouth, eyes and genitals.

Also contact your doctor immediately if you notice any of the following side effects:

- unusual fast or irregular heartbeat
- chest pain.

Other side effects

Common: may affect up to 1 in 10 people

- constipation
- dry mouth
- nausea
- vomiting
- stomach discomfort after meal (dyspepsia)
- abdominal pains
- epigastric pains
- anorexia
- diarrhoea
- taste disturbance
- dry cough
- difficulty breathing
- vision disturbances
- ringing or buzzing in the ears
- muscle cramps
- feeling of weakness (asthenia)
- low blood pressure and dizziness, fainting on standing up
- headache
- feelings of dizziness
- sensations of tickling, itching or tingling without an apparent cause (paresthesia)
- spinning sensation (vertigo)
- skin reactions (rash, raised rash eruptions, itching)
- low potassium blood levels.

Uncommon: may affect up to 1 in 100 people

- purple skin patches (purpura)
- skin itchy rash (urticaria)
- mood disturbances and/or sleep disturbances
- difficulty breathing with wheezing or coughing (bronchospasm)
- swelling of the face, lips, mouth, tongue, eyes or throat
- kidney disorder (renal insufficiency)
- impotence
- sweating.

If you already suffer from *systemic lupus erythematosus* (a type of collagen disease) this might get worse.

Rare: may affect up to 1 in 1,000

- elevated plasma calcium levels
- intestinal angioedema (presented with abdominal pain with or without nausea or vomiting)
- psoriasis worsening.

Very rare: may affect up to 1 in 10,000 people

- pancreas inflammation (pancreatitis)
- reduction in the number of platelets
- reduction in the number of white blood cells, which makes infections more likely
- reduction in the number of red blood cells which can make the skin pale and cause weakness or breathlessness (anaemia in patients who have had kidney transplants, or in patients undergoing haemodialysis, aplastic anaemia, haemolytic anaemia)
- liver inflammation (hepatitis)
- kidney disorder with severely decreased urine output (acute renal failure)
- pneumonia
- nasal stuffiness or runny nose
- heart disorders (slow or unusual fast or irregular heartbeat, chest pain or heart attack)
- severe skin reactions (manifested as rash, skin reddening, blistering of lips, eyes or mouth, skin peeling with or without fever)
- increased sensitivity of the skin to sunlight
- confusion.

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

- in case of liver failure (liver problems), there is a possibility of a brain disorders (personality change, confusion, stupor, tremor, convulsions, confusion, impaired consciousness)
- changes in laboratory parameters seen on blood tests.

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 Plus

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.

Alu/Alu blisters

Do not store above 30°C. Store in the original package in order to protect from light and moisture.

PVC / PVDC / Al blister in Al bag with added desiccant

Do not swallow the desiccant.

Do not store above 30°C. Store in the original package in order to protect from light and moisture.

After first opening the bag: 6 months

After opening the bag do not store above 25°C.

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 Plus contains

The active substances are perindopril erbumine and indapamide. Each tablet contains 4.00 mg of perindopril erbumine, equivalent to 3.338 mg perindopril, and 1.25 mg of indapamide.

The other ingredients are:

hydroxypropylbetadex, lactose monohydrate, povidone K25, silicified microcrystalline cellulose, colloidal silica hydrated, colloidal anhydrous silica, magnesium stearate.

Pendrex Plus contains lactose. For further information see section 2.

What Pendrex Plus looks like and contents of the pack

Pendrex Plus 4 mg/1.25 mg tablets

White, oblong, biconvex tablet debossed with PI on the one side.

Alu/Alu blister

PVC / PVDC // Al blister in Al bag with added desiccant.

Pack sizes: 7, 14, 20, 28, 30, 50, 56, 60, 90, 98, 100 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.

Salutas Pharma GmbH, Dieselstrasse 5, 70839

Gerlingen, Germany.

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

Germany: Perindopril HEXAL plus Indapamid

4 mg / 1,25 mg Tabletten

Ireland: Pendrex Plus 4mg/1.25mg Tablets

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