Leaflet Artwork for Perindopril Tablets Pack Rudipharam Cold form

170 mm

440 mm

Dummy Pharma code

Package leaflet: Information for the patient

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

Read all of these 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 or nurse.
- 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 pharmacist or nurse.

What is in this leaflet

1. What Perindopril Erbumine Tablets are and what they are used for
2. What you need to know before you take Perindopril Erbumine Tablets
3. How to take Perindopril Erbumine Tablets
4. Possible side effects
5. How to store Perindopril Erbumine Tablets
6. Contents of the pack and other information

1. What Perindopril Erbumine Tablets are and what they are used for

Perindopril Erbumine Tablets contain the active substance perindopril erbumine which belongs to a group of medicines known as angiotensin converting enzyme (ACE) inhibitors. These work by making your blood vessels wider, which makes it easier for your heart to pump blood through them.

Perindopril Erbumine Tablets is 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 Perindopril Erbumine Tablets

Do not take Perindopril Erbumine Tablets if:
- 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 experienced symptoms such as wheezing, swelling of the face, tongue or throat, intense itching or severe skin rashes, fainting or dizziness 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 Erbumine in early pregnancy – see pregnancy and breast feeding 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, Perindopril Erbumine 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 being treated with sacubitril/valsartan, a medicine for heart failure as the risk of angioedema (rapid swelling under the skin in an area such as the throat) is increased (see "Warnings and Precautions" and "Other medicines and Perindopril Erbumine")

Warnings and precautions

If any of the following apply to you please talk to your doctor or pharmacist or nurse before taking Perindopril Erbumine Tablets 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);
- have any other heart problems;
- have liver problems;
- have kidney problems or if you are receiving dialysis;
- have abnormally increased levels of a hormone called aldosterone in your blood (primary aldosteronism);
- suffer from a collagen vascular disease (disease of the connective tissue) such as systemic lupus erythematosus or scleroderma;
- have diabetes;
- are on a salt restricted diet or use salt substitutes which contain potassium;
- are to undergo anaesthesia and/or major surgery;
- are to undergo LDL apheresis (which is the 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;
- have recently suffered from diarrhoea or vomiting, or are dehydrated;
- have been told by your doctor that you have an intolerance to some sugars;
- 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 Erbumine".
- 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
- 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 and for cancer),
  - ❖ linagliptin, saxagliptin, sitagliptin, vildagliptin and other drugs belonging to the class of the also called gliptins (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 Erbumine Tablets. This may occur at any time during treatment. If you develop such symptoms, you should stop taking Perindopril Erbumine Tablets and see a doctor immediately. See also section 4.

You must tell your doctor if you think you are (or might become) pregnant. Perindopril Erbumine 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 erbumine tablets is not recommended for use in children and adolescents less than 18 years old.

Other medicines and Perindopril Erbumine Tablets

Please tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines, including medicines obtained without a prescription.

Perindopril erbumine tablets can affect the way some other medicines work, and some medicines can have an effect on Perindopril Erbumine Tablets. In particular, tell your doctor if you are using any of the following medicines:
- other medicines for high blood pressure, including angiotensin II receptor blockers (ARB), aliskiren (see also information under the headings "Do not take Perindopril Erbumine" and "Warnings and precautions") or diuretics (medicines which increase the amount of urine produced by the kidneys);
- potassium-sparing medicines (e.g. triamterene, amiloride), potassium supplements or potassium containing salt substitutes, other drugs which can increase potassium in your body (such as heparin, a medicine used to thin blood to prevent clots; trimethoprim and co-trimoxazole also known as trimethoprim/sulfamethoxazole for infections caused by bacteria);
- potassium-sparing medicines used in the treatment of heart failure (e.g. eplerenone, spironolactone at doses between 12.5 mg and 50 mg per day);
- lithium (a medicine for mental health problems such as mania or depression);
- non-steroidal anti-inflammatory drugs (e.g. ibuprofen) for pain relief or high dose aspirin;
- medicines to treat diabetes (such as insulin or metformin) to lower blood sugar;
- baclofen (used to treat muscle stiffness in diseases such as multiple sclerosis);
- medicines to treat mental disorders such as depression, anxiety or schizophrenia or other psychoses; (e.g. tricyclic antidepressants, antipsychotics),
- immunosuppressants (medicines which reduce the defence mechanism of the body), used for the treatment of auto-immune disorders (e.g. rheumatoid arthritis) or following transplant surgery (e.g. ciclosporin, tacrolimus),
- trimethoprim (used for the treatment of infections)
- estramustine (used in cancer therapy)
- 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",
- sacubitril/valsartan (used to treat long-term heart failure). See sections "Do not take Perindopril Erbumine" and "Warnings and precautions".
- medicines for the treatment of gout (e.g. allopurinol),
- medicines for the treatment of an irregular heartbeat (e.g. procainamide),
- medicines that make the blood vessels become wider (i.e. vasodilators, including nitroglycerin and other nitrates),
- medicines used for the treatment of low blood pressure, shock or asthma (e.g. ephedrine, noradrenaline or adrenaline).
- gold salts, especially with intravenous administration (used to treat symptoms of rheumatoid arthritis)

Ask your doctor if you are not sure what these medicines are. If you go into hospital, let the medical staff know you are taking Perindopril Erbumine Tablets.

Perindopril Erbumine with food and drink

It is preferable to take Perindopril Erbumine before a meal.

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 Perindopril Erbumine tablets before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Perindopril Erbumine Tablets. Perindopril Erbumine tablets 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. Perindopril Erbumine tablets 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 Erbumine 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 to operate machinery may be impaired. Do not drive or use machinery if you experience dizziness or weariness while taking Perindopril. If this occurs, you should talk to your doctor.

Perindopril Erbumine Tablets contains lactose

Perindopril Erbumine tablets contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Perindopril Erbumine 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 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 and any increase in the dose depending on your condition and whether you are taking any other medicines.

Method of administration:

The recommended dose for Perindopril Erbumine tablets is:

High blood pressure:

Adults- The recommended starting and maintenance dose is 4 mg once daily. After one month, this can be increased to 8 mg once a day if required. The maximum recommended dose for high blood pressure is 8 mg a day.

Elderly patients with high blood pressure:

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

Heart failure:

Adults and the elderly: 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:

Adults- The recommended starting dose is 4 mg once daily. After two weeks, this can be increased to 8 mg once a day, which is the maximum recommended dose for this indication.

Elderly patients with stable coronary artery disease:

If you are 65 years old or older, the recommended 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 8 mg once daily.

Use in children and adolescents

Use in children and adolescents is not recommended.

If you take more Perindopril Erbumine tablets than you should

If you take too many tablets, contact your nearest hospital accident and emergency department or tell your doctor **immediately**. 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 Erbumine Tablets

It is important to take your medicine every day as regular treatment works better. However, if you forget to take a dose of Perindopril Erbumine tablets, 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 Erbumine Tablets

As the treatment with Perindopril Erbumine tablets is usually life-long, you should discuss with your doctor before stopping this medicinal product.

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

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:

Common (may affect up to 1 in 100 people):
- severe dizziness or fainting due to low blood pressure.

Uncommon (may affect up to 1 in 100 people):
- swelling of the face, lips, mouth, tongue or throat, difficulty in breathing (angioedema)
- sudden wheeziness, chest pain, shortness of breath, or difficulty breathing (bronchospasm)

Very rare (may affect up to 1 in 10,000 people):
- unusual fast or irregular heartbeat, chest pain (angina) or heart attack
- weakness of arms or legs, or problems speaking which could be sign of a possible stroke
- inflamed pancreas which may cause severe abdominal and back pain accompanied with feeling very unwell
- yellowing of the skin or eyes (jaundice) which could be a sign of liver problems (hepatitis)
- skin rash which often starts with red itchy patches on your face, arms or legs (erythema multiforme)

Other possible side effects:

Common (may affect up to 1 in 10 people):
- headache,
- dizziness,
- vertigo,
- pins and needles,
- vision disturbances,
- cough,
- shortness of breath,
- muscle cramps,
- tinnitus (sensation of noises in the ears),
- gastro-intestinal disorders (nausea (feeling sick), vomiting (being sick), abdominal pain, taste disturbances, indigestion, diarrhoea, constipation),
- allergic reactions (such as skin rashes, itching),
- feeling of weakness or tiredness.

Uncommon (may affect up to 1 in 100 people):
- mood swings
- sleep disturbances,
- dry mouth,
- impotence,
- excessive sweating,
- somnolence,
- fainting,
- palpitations,
- tachycardia,
- malaise
- arthralgia (joint pain),
- myalgia (muscle pain),
- chest pain,
- fever,
- fall,
- depression
- intense itching or severe skin rash,
- renal insufficiency (poor function of the kidneys)
- formation of blister clusters over the skin,
- excess of eosinophils in the blood (a type of white blood cell).
- vasculitis (inflammation of blood vessels),
- photosensitivity reaction (increased sensitivity of the skin to sun),
- peripheral oedema (swelling of the hands or feet/ankles),
- change in laboratory parameters: high level of potassium in the blood (reversible on discontinuation), low level of sodium in the blood
- hypoglycaemia (very low blood sugar level). This is important in case of diabetic patients, increased blood urea, and increased blood creatinine,

Rare (may affect up to 1 in 1000 people):
- increased level of liver enzymes, high level of serum bilirubin. This may show up in blood tests.
- 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 (kidney 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),
- disorders of the blood such as a lower number of white and red blood cells, lower haemoglobin, lower number of blood platelets.

If you have these symptoms contact your doctors as soon as possible.

Frequency 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the 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 Erbumine Tablets
- Keep this medicine out of the sight and reach of children.
- Do not use this your medicine after the expiry date printed on the carton and label. The expiry date refers to the last day of that month.
- Store below 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 Perindopril Erbumine Tablet contains

The active substance is perindopril erbumine.

2 mg: Each film-coated tablet contains Perindopril Erbumine 2 mg

The other ingredients are:

Core tablet: lactose monohydrate, microcrystalline cellulose, sodium hydrogen carbonate, crospovidone, amino methacrylate copolymer, colloidal anhydrous silica, magnesium stearate.

Film-coating: hypromellose, titanium dioxide, macrogols, magnesium stearate, glycerine.

4 mg: Each film-coated tablet contains Perindopril Erbumine 4 mg

The other ingredients are:

Core tablet: lactose monohydrate, microcrystalline cellulose, sodium hydrogen carbonate, crospovidone, amino methacrylate copolymer, colloidal anhydrous silica, magnesium stearate.

Film-coating: hypromellose, titanium dioxide, macrogols, magnesium stearate, glycerine.

8 mg: Each film-coated tablet contains Perindopril Erbumine 8 mg

The other ingredients are:

Core tablet: lactose monohydrate, microcrystalline cellulose, sodium hydrogen carbonate, crospovidone, amino methacrylate copolymer, colloidal anhydrous silica, magnesium stearate.

Film-coating: hypromellose, titanium dioxide, macrogols, magnesium stearate, glycerine.

What Perindopril Erbumine Tablets looks like and contents of the pack

2 mg: White to off-white, round, film coated, biconvex tablets engraved with 'P2' on one side and plain on other side. Diameter: 5.10 mm.

4 mg: White to off-white, rod-shaped, film-coated breakable tablets engraved with 'P4' on one side and plain on other side and scored on both edges. The tablet can be divided into equal doses. Dimension: 8.10 mm x 4.10 mm.

8 mg: White to off-whited, round, film coated biconvex tablets engraved with heart-shape 'P8' on one side and plain on the other side. Diameter: 8.10 mm.

Perindopril Erbumine Tablets are available in Alu/PVC/PE/ACLAR blister and Alu-Alu blister packs of 30 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder **POM**

Rudipharm Limited
Unit 6, Salbrook Road Industrial Estate
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Manufacturer
Rudipharm Limited
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To listen to or request a copy of this leaflet in Braille, large print or audio please call,

01293 827819 (UK only)

Please be ready to give the following information:

Product name	Reference number
Perindopril Erbumine 2mg Tablets	PL 49565/0046
Perindopril Erbumine 4mg Tablets	PL 49565/0047
Perindopril Erbumine 8mg Tablets	PL 49565/0048

This leaflet was last revised in September 2026.

Product Name : KLD's for Perindopril Tablets Pack Rudipharam Cold form

Carton Size : 170 x 440 mm

Printing Color : **Black**

Artwork Code : 20xxxx
Pharma Code : xxx

K Line Color : Die-cut

Losartan Tablets
Font type: Times New Roman
Headings: 13pt (Bold)
Sub-Heading: 9pt (Bold)
Normal Text: 9pt (Regular)

Pantone 715 C
Pantone 368 C
Black