



Package leaflet: Information for the patient

Perindopril Erbumine 2 mg, 4 mg and 8 mg Film-coated 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, 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 Perindopril Erbumine Tablets are and what they are used for
2. What you need to know before you take Perindopril Erbumine Tablets
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1. What Perindopril Erbumine Tablets are and what they are used for

Perindopril Erbumine Tablets are an angiotensin converting enzyme (ACE) inhibitor. These work by widening the blood vessels, which makes it easier for your heart to pump blood through them.

Perindopril Erbumine 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 Perindopril Erbumine Tablets

Do not take Perindopril Erbumine Tablets:

- if you are allergic to perindopril erbumine 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 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 Tablets in early pregnancy - see pregnancy 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 Tablets 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 (see "Warnings and Precautions" and "Other medicines and Perindopril Erbumine Tablets").

Warnings and precautions

Talk to your doctor, 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 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 Tablets".

- 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).
- ❖ 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 that you are (or might become) pregnant. Perindopril Erbumine Tablets are 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 and breast-feeding section).

Children and adolescents

Perindopril Erbumine Tablets are not recommended for use in children and adolescents up to the age of 18 years.

Other medicines and Perindopril Erbumine Tablets

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

Treatment with Perindopril Erbumine Tablets can be affected by other medicines. Your doctor may need to change your dose and/or to take other precautions. These include:

- other medicines for high blood pressure, including angiotensin II receptor blockers (ARB), aliskiren (see also information under the headings "Do not take Perindopril Erbumine Tablets" and "Warnings and precautions") or diuretics (medicines which increase the amount of urine produced by the kidneys),
- potassium-sparing drugs (e.g. triamterene, amiloride), potassium supplements or potassium-containing salt substitutes, other drugs which can increase potassium in your body (such as heparin and co-trimoxazole also known as trimethoprim/sulfamethoxazole),
- potassium-sparing drugs used in the treatment of heart failure: eplerenone and spironolactone at doses between 12.5 mg to 50 mg per day,
- lithium for 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),
- baclofen (used to treat muscle stiffness in diseases such as multiple sclerosis),
- medicines to treat mental disorders such as depression, anxiety, schizophrenia etc (e.g. tricyclic antidepressants, antipsychotics),
- immunosuppressants (medicines which reduce the defence mechanism of the body) used for the treatment of auto-immune disorders or following transplant surgery (e.g. ciclosporin, tacrolimus),
- trimethoprim (used for the treatment of infections),
- estramustine (used in cancer therapy),
- 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",
- sacubitril/valsartan (used to treat long-term heart failure). See sections "Do not take Perindopril Erbumine Tablets" and "Warnings and precautions",
- allopurinol (for the treatment of gout),
- procainamide (for the treatment of an irregular heart beat),
- vasodilators including nitrates (products that make the blood vessels become wider),
- 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 arthritis).

Perindopril Erbumine Tablets with food and drink

It is preferable to take Perindopril Erbumine Tablets 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 are 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 are 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 do 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.

Perindopril Erbumine Tablets contain lactose

Perindopril Erbumine Tablets contain 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.

The recommended dosages for Perindopril Erbumine Tablets are as follows:

High blood pressure:

The usual 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 usual 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:

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:

The usual 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 usual 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.

Patients with kidney problems:

If you have kidney problems, your doctor will alter the dose depending on how well your kidneys are working.

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 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. Other side effects may include: kidney failure, shock, imbalance of minerals in the body, rapid or deep breathing, increase in heart rate, irregular heartbeat, slowing of heart rate, anxiety and cough.

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 10 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) (See section 2 "Warnings and precautions"),
- sudden wheeziness, chest pain, shortness of breath, or difficulty in 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 a 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 hepatitis,
- skin rash which often starts with red itchy patches on your face, arms or legs (erythema multiforme)

Tell your doctor if you notice any of the following side effects:

Common (may affect up to 1 in 10 people):

- headache, • dizziness,
- vertigo, • pins and needles,
- vision disturbances, • tinnitus (sensation of noises in the ears),
- cough, • shortness of breath (dyspnoea),
- gastrointestinal disorders (nausea (feeling sick), vomiting (being sick), abdominal pain, taste disturbances, dyspepsia or indigestion, diarrhoea, constipation),
- allergic reactions (such as skin rashes, itching),
- muscle cramps, • feeling of weakness or tiredness.

Uncommon (may affect up to 1 in 100 people):

- mood swings, • sleep disturbances,
- dry mouth, • intense itching or severe skin rashes,
- formation of blister clusters over the skin,
- kidney problems, • impotence,
- sweating,
- excess of eosinophils (a type of white blood cell). This may show up in blood tests,
- somnolence, • fainting,
- palpitations, • tachycardia,
- vasculitis (inflammation of blood vessels),
- photosensitivity reaction (increased sensitivity of the skin to sun),
- arthralgia (joint pain),

- myalgia (muscle pain),
- chest pain, • malaise,
- peripheral oedema (swelling of the hands or feet/ankles),
- fever, • fall,
- change in laboratory parameters: high blood level of potassium reversible on discontinuation, low level of sodium, hypoglycaemia (very low blood sugar level) in case of diabetic patients, increased blood urea, and increased blood creatinine.

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

- changes in laboratory parameters: increased level of liver enzymes, high level of serum bilirubin,
- psoriasis worsening

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),
- acute renal failure,
- changes in blood values such as a lower number of white and red blood cells, lower haemoglobin, lower number of blood platelets. Concentrated urine (dark in colour), feel or are sick, have muscle cramps, confusion and fits which may be due to inappropriate ADH (anti-diuretic hormone) secretion can occur with ACE inhibitors. If you have these symptoms contact your doctor 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 medicine after the expiry date which is stated 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 Tablets contain

The active substance is perindopril erbumine.

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

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

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, eudragit EPO, colloidal anhydrous silica, magnesium stearate.

Film-coating: hypromellose, titanium dioxide, macrogols, magnesium stearate, glycerine. The 4 mg and 8 mg tablets also contain copper chlorophyllin.

What Perindopril Erbumine Tablets look 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: Light green colored, rod-shaped, film-coated breakable tablets engraved with 'P4' on one side and plain on other side and scored on both edges (dimensions: 8.10 mm x 4.10 mm). The tablet can be divided into equal doses.

8 mg: Green colored, 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 packs of 30 tablets.

POM

Marketing Authorisation Holder and Manufacturer:

MEDREICH PLC
Warwick House, Plane Tree Crescent,
Feltham TW13 7HF, UK
E-mail : info@medreich.co.uk

To listen to or request a copy of this leaflet in Braille, large print or audio please call,

02088311580 (UK only)

Please be ready to give the following information:

Product name	Reference number
Perindopril Erbumine 2 mg Film-coated Tablets	PL 21880/0215
Perindopril Erbumine 4 mg Film-coated Tablets	PL 21880/0216
Perindopril Erbumine 8 mg Film-coated Tablets	PL 21880/0217

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