PACKAGE LEAFLET

Package leaflet: Information for the patient

Perindopril Erbumine 2 mg Tablets
Perindopril Erbumine 4 mg Tablets
perindopril *tert*-butylamine

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 is and what it is 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 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 blood vessels supplying it.

2. What you need to know before you take Perindopril Erbumine

Do not take Perindopril Erbumine:

- if you are allergic to perindopril, to any other ACE inhibitor or to any of the other ingredients of this medicine (listed in section 6),
- if you are more than 3 months pregnant (it is also better to avoid perindopril in early pregnancy - see pregnancy section),
- 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 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 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).

Warnings and precautions

Talk to your doctor or pharmacist before taking Perindopril Erbumine 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, and are taking antidiabetic medicines, including insulin to control your diabetes (your blood should be monitored for low blood glucose levels, especially during the first month of treatment)
- are on a salt restricted diet or use salt substitutes which contain potassium,
- have recently suffered from diarrhoea or vomiting, or are dehydrated,
- 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 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
- are taking any of the following medicines, the risk of angioedema (rapid swelling under the skin in areas such as the throat) is increased:
  - racecadotril (used to treat diarrhoea)
  - medicines used to prevent organ transplant rejection and for cancer (e.g., temsirolimus, sirolimus, everolimus).
  - vildagliptin, a medicine used to treat diabetes.

Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals.

<u>Angioedema</u>
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. This may occur at any time during treatment. If you develop such symptoms you should stop taking Perindopril Erbumine and see a doctor immediately. See also section 4.

See also information under the heading “Do not take Perindopril Erbumine”

During treatment tell your doctor or pharmacist:
- if you develop signs of an infection (e.g. sore throat, fever)
- if you develop yellowing of the skin or whites of the eyes (jaundice)
- if you are to undergo anaesthesia and/or major surgery,
- if you are to undergo LDL apheresis (which is removal of cholesterol from your blood by a machine),
- if you are going to have desensitisation treatment to reduce the effects of an allergy to bee or wasp stings,

- if you think that 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 and breast-feeding section).

Children and adolescents
Perindopril erbumine is not recommended for use in children and adolescents less than 18 years old.

Other medicines and Perindopril Erbumine

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

Perindopril erbumine can affect the way some other medicines work and some medicines can have an effect on Perindopril Erbumine. In particular, tell your doctor if you are using any of the following medicines:

- other medicines for high blood pressure, including 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,
- 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), other medicines which can increase potassium in your body (such as co-trimoxazole also known as trimethoprim/sulfamethoxazole),
- lithium (a medicine for mental health problems such as mania or depression)
- non-steroidal anti-inflammatory drugs (e.g. ibuprofen, diclofenac) for pain relief or high dose aspirin,
- medicines to treat diabetes (such as gliptins, insulin or metformin),
- baclofen (used to treat muscle stiffness in diseases such as multiple sclerosis)
- medicines to treat mental disorders such as depression, anxiety or schizophrenia (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 for the treatment of gout (e.g. allopurinol),
- medicines for the treatment of an irregular heart beat (e.g. procainamide),
- medicines that make the blood vessels become wider (i.e. vasodilators, including nitroglycerin and other nitrates),
- medicines used to thin blood (e.g. heparin),
- 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)

Treatment with Perindopril Erbumine can be affected by other medicines. Your doctor may need to change your dose and/or to take other precautions. These include:
- if you are taking an angiotensin II receptor blocker (ARB) or aliskiren (see also information under the headings “Do not take Perindopril Erbumine” and “Warnings and precautions”).
- 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, a medicine used to treat a type of long-term (chronic) heart failure in adults, see also section “Do not take Perindopril Erbumine”.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you maybe 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 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. Perindopril Erbumine 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 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 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.

Perindopril Erbumine contains Lactose

Perindopril Erbumine contains **lactose**. If you have been told by your doctor that you have an intolerance to some sugars, such as lactose, contact your doctor before taking this medicinal product.
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'

3. How to take Perindopril Erbumine

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 and before a meal. Your doctor will decide on the correct dose for you. The 4 mg tablet can be divided into equal doses.

The recommended dose for Perindopril Erbumine is:

High blood pressure:
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:
The recommended 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 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.

Patients with kidney problems:

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

If you take more Perindopril Erbumine 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 heart-beat, slowing of heart rate, anxiety and cough.

If you forget to take Perindopril Erbumine

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, 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

As the treatment with perindopril erbumine is usually life-long, you should discuss with your doctor before stopping 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.

If you experience any of the following side effects, stop taking this medicine at once and tell your doctor or go to the nearest hospital casualty department immediately:

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),
- tightening of the chest, wheezing and shortness of breath (bronchospasm),
- intense itching or severe skin rash, formation of blister clusters over the skin (pemphigoid)
- producing little or no urine, cloudy urine, pain when passing urine or lower back pain (these may be signs of serious problems with your kidneys)

Very rare (may affect up to 1 in 10,000 people):
- unusual fast or irregular heart-beat, 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
- skin rash which often starts with red itchy patches on your face, arms or legs (erythema multiforme)
- disorders of the blood, such as decreased number of all or certain blood cell types – you may notice a pale skin colour, headache, an increase in infections such as sore throat, mouth ulcers etc. with fever, an increase in unexpected bruising or bleeding, or feel tired, dizzy, breathless and weak.
- eosinophilic pneumonia (a rare type of pneumonia). You may develop cough, high temperature and have difficulty breathing.

Other possible 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),
- light-headedness due to low blood pressure,
- cough, shortness of breath,
- gastro-intestinal disorders (nausea (feeling sick), vomiting (being sick), abdominal pain, taste disturbances, 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
- depression
- fast heart rate, thump in the chest
- sleep disturbances,
- dry mouth,
- impotence,
- excessive sweating
- excess of eosinophils in the blood (a type of white blood cell). This may show up in blood tests.
- somnolence
- fainting
- vasculitis (inflammation of blood vessels)
- photosensitivity reaction (increased sensitivity of the skin to sun)
- arthralgia (joint pain), myalgia (muscle pain)
- chest pain
- peripheral oedema (swelling of the hands or feet/ankles)
- fever
- fall
- 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.

These may show up in blood tests.

Rare (may affect up to 1 in 1,000 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

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

- confusion,
- rhinitis (blocked up or runny nose),
- disorders of the blood such as a lower number of red blood cells, lower haemoglobin, lower number of blood platelets.

Not known (cannot be estimated from available data):

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

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

Reporting of side effects
If you get any side effects talk to your doctor or pharmacist. 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

Keep this medicine out of the sight and reach of children.

Do not store above 25 °C.

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

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 contains

The active substance is perindopril tert-butylamine.
One 2 mg tablet contains 2 mg of perindopril *tert*-butylamine, equivalent to 1.669 mg of perindopril.
One 4 mg tablet contains 4 mg of perindopril *tert*-butylamine, equivalent to 3.338 mg of perindopril.

The other ingredients are:

Lactose See section 2 'Perindopril Erbumine contains lactose', magnesium stearate, anhydrous colloidal silica, cellulose, microcrystalline, sodium hydrogen carbonate, aluminium lake of sodium copper chlorophyllin E141.

What Perindopril Erbumine looks like and contents of the pack

Perindopril Erbumine 2 mg tablets are green mottled, round, biconvex tablets marked with "PT" over "2" on one side of the tablet and "M" on the other side.

Perindopril Erbumine 4 mg tablets are green mottled, capsule shaped, biconvex tablets with side notch, marked with "PT4" on one side of the tablet and "M" on the other side.

Perindopril Erbumine is available in blisters of 14, 30, 60, 90 and 100 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder:

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Manufacturer:

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This leaflet was last revised in 05/2022.