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Package leaflet: Information for the user

Perindopril 8 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

The name of your medicine is Perindopril 8 mg tablets (referred to as 'Perindopril Tablets' or 'Perindopril' throughout this leaflet).

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

1. What Perindopril tablets is and what it is used for

Perindopril Tablets is 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 Tablets is used:

- to treat **high blood pressure** (hypertension),
- 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 tablets

Do not take Perindopril Tablets

- if you are allergic to perindopril or to any of the other ingredients of this medicine (listed in section 6) or any other ACE inhibitor,
- if you are more than 3 months pregnant. (It is also better to avoid Perindopril Tablets 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 diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.
- 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 are having dialysis or any other type of blood filtration. Depending on the machine that is used, perindopril 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

If any of the following apply to you please talk to your doctor or pharmacist before taking Perindopril 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),
- if you have any other heart or liver or kidney problems, or if you are receiving dialysis;
- if you have abnormally increased levels of a hormone called aldosterone in your blood (primary aldosteronism),
- if you suffer from a collagen vascular disease such as systemic lupus erythematosus or scleroderma,
- if you are on a salt restricted diet or use salt substitutes which contain potassium,
- if you suffer from diabetes which is not well controlled;
- if you are to undergo anaesthesia and/or major surgery,
- if you have suffered from recent diarrhoea or vomiting, or are dehydrated,
- if you are going to have desensitisation 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 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 Perindopril Tablets"

- if you are of black origin since you may have a higher risk of angioedema (rapid swelling under the skin in an area such as the throat) and this medicine may be less effective in lowering your blood pressure than in non-black patients.

- if you are taking any of the following medicines, the risk of angioedema is increased:
 - racecadotril (a medicine 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
 - sacubitril (available as fixed-dose combination with valsartan), used to treat long-term heart failure.

Children and adolescents

The use of Perindopril in children and adolescents up to the age of 18 years is not recommended.

Other medicines and Perindopril Tablets

Tell your doctor or pharmacist if you have recently taken or might take any other medicines including medicines obtained without a prescription.

Treatment with Perindopril 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 treating high blood pressure, including angiotensin II receptor blocker (ARB) or aliskiren (see also information under the headings "Do not take Perindopril tablets" and "Warnings and precautions") or diuretics (water tablets, medicines which increase the amount of urine produced by the kidneys);
- Potassium supplements (including salt substitutes), potassium-sparing diuretics and other medicines that can increase the amount of potassium in your blood (e.g. trimethoprim and co-trimoxazole 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)
- medicines for the treatment of diabetes (such as insulin or metformin) to lower blood sugar;
- baclofen (used to treat muscle stiffness in diseases such as multiple sclerosis),
- lithium for mania or depression,
- medicines to treat mental disorders such as depression, anxiety, schizophrenia or other psychoses (e.g. tricyclic antidepressants, antipsychotics),
- allopurinol used for the treatment of gout,
- immunosuppressants (medicines which reduce the defence mechanism of the body) used for the treatment of auto-immune disorders (eg rheumatoid arthritis) or following transplant surgery (e.g. ciclosporin, tacrolimus),
- trimethoprim (for the treatment of infections);
- estramustine (used in cancer therapy);
- medicines, which is most often used to treat diarrhea (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 " and "Warnings and precautions",
- procainamide, a treatment of irregular heart beat,
- non-steroidal anti-inflammatory drugs (NSAIDs, e.g. ibuprofen) for pain relief, including high dose aspirin;
- medicines used for the treatment of low blood pressure, shock or asthma (e.g. ephedrine, noradrenaline or adrenaline).
- vasodilators including nitrates (products that make the blood vessels become wider);
- heparin (medicines used to thin blood),
- gold salts, especially with intravenous administration (used to treat symptoms of rheumatoid arthritis).

Perindopril Tablets with food and drink

It is preferable to take Perindopril Tablets before a meal.

Pregnancy, breast-feeding and fertility

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 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 Tablets. Perindopril 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 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 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.

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

3. How to take Perindopril 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.

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The recommended dosages are as follows:

High blood pressure: The usual starting and maintenance dose for treatment in adults is 4 mg once daily. After a month, this can be increased to 8 mg a day which is the maximum recommended dose for high blood pressure. If you are 65 or older, the usual starting dose is 2 mg once a day. After a month this can be increased to 4 mg a day and then if necessary to 8 mg once daily.

Stable coronary artery disease: The usual starting dose is 4 mg once daily. After two weeks, this can be increased to 8 mg once daily, which is the maximum recommended dose in this indication. If you are 65 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.

Use in children and adolescents

Use in children and adolescents is not recommended.

If you take more Perindopril Tablets than you should

If you have taken 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 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 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 Tablets

As the treatment with Perindopril 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 or pharmacist.

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 "Warning and precaution"),
- 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),
- gastro-intestinal disorders (nausea, vomiting, abdominal pain, taste disturbances, dyspepsia or difficulty of digestion, diarrhoea, constipation),
- allergic reactions (such as skin rashes, itching),
- muscle cramps,
- feeling of weakness.

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 cells),
- 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,
- oedema peripheral,
- 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.
- depression

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

- psoriasis worsening,
- changes in laboratory parameters: Increased level of liver enzymes, high level of serum bilirubin.
- 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,
- eosinophilic pneumonia (a rare type of pneumonia),
- rhinitis (blocked up or runny nose),
- changes in blood values 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 doctor as soon as possible.

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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

The United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

5. How to store Perindopril tablets

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

Store in the original package in order to protect from moisture and light.

Do not store above 25°C

Use within 60 days after first opening the Aluminium pouch.

Aluminium pouch contains desiccant, do not swallow the desiccant.

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 the 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 Tablets contains

- The active substance is perindopril tert-butylamine. Each tablet contains 8 mg of perindopril tert-butylamine, equivalent to 6.676 mg perindopril.
- The other ingredients are: Lactose, silica colloidal anhydrous (E551), cellulose, microcrystalline (E460) and magnesium stearate (E572).

What Perindopril Tablets looks like and contents of the pack

Tablet

Perindopril Tablets 8 mg tablets are white to off-white, coloured round biconvex, uncoated tablets with debossing "D" on one side and "5" & "9" on either side of the break line on another side. The tablet can be divided into two equal halves.

Perindopril Tablets tablets are available in blister packs of 28, 30, 56, 60, 84, 90, 112 and 120 tablets.

The blisters are packed in a foil pouch containing a desiccant. Each foil pouch contains 28 or 30 tablets. Do not swallow desiccant.

Not all pack sizes may be marketed.

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