direction of reading PhC

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Package leaflet: Information for the patient

Perindopril 2 mg
tablets
Perindopril 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 is and what it is used for

The active substance of Perindopril tablets belongs to the group of medicines called angiotensin converting enzyme (ACE) inhibitors.

Perindopril tablets are used:
- to treat high blood pressure (hypertension);
- to treat symptomatic 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

Do not take Perindopril
- if you are allergic to perindopril, to any of the other ingredients of this medicine (listed in section 6) or to any other ACE inhibitor;
- if you have in the past a hypersensitivity reaction with sudden swelling of the lips and face, neck, possibly also hands and feet, or suffocation or hoarseness (angioedema) after use of an ACE inhibitor;
- if someone in your family or you have had angioedema in any other circumstances;
- if you are more than 3 months pregnant. (It is also better to avoid Perindopril 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 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 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.

Warnings and precautions

Talk to your doctor or pharmacist before taking Perindopril.

It is possible that Perindopril is not convenient for you, or a personal control is needed regularly. Therefore, before starting to take Perindopril tablets, inform your doctor on the following:
- if you have been told that you have aortic stenosis (narrowing of the main blood vessel leading from the heart), your heart muscle is enlarged or you have a problem with the valves of your heart;
- if you have been told that you have narrowing of the artery supplying the kidney with blood (renal artery stenosis);
- if you have abnormally increased levels of a hormone called aldosterone in your blood (primary aldosteronism);
- if you have diabetes;
- if you are suffering from any other kidney, liver or heart disease;
- if you are receiving hemodialysis or have had recent kidney transplantation;
- if you suffer from a collagen vascular disease (disease of the connective tissue) such as systemic lupus erythematosus or scleroderma;
- if you are on a salt restriction diet, or have suffered from excessive vomiting or diarrhoea or have used medicines that increase the amount of urine (diuretics);
- if you are taking lithium, medicine used for the treatment of mania or depression;
- if you are taking potassium supplements or potassium containing salt substitutes;
- 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".
- if you are taking any of the following medicines, the risk of angioedema (rapid swelling under the skin in area such as the throat) may be increased:
  - racecadotril (used to treat diarrhea),
  - 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),
  - vildagliptin (used to treat diabetes).
- if you 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.
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren;

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. This may occur at any time during treatment. If you develop such symptoms, you should stop taking Perindopril and see a doctor immediately. See also section 4.

You must tell your doctor if you think you are (or might become) pregnant. Perindopril 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).

If you develop any of the following symptoms you should let your doctor know immediately:
- You feel dizzy after your first dose. A few people react to their first dose or when their dose is increased by feeling dizzy, weak, faint and sick.
- Fever, sore throat or mouth ulcers (these may be symptoms of infection caused by the lowering of the number of white blood cells).
- Yellowing of the skin and whites of eyes (jaundice) that may be sign of liver disease.
- A dry cough which is persistent for a long time. Cough has been reported with the use of ACE inhibitors but may be also a symptom of other upper respiratory tract disease.

At the beginning of treatment and/or during the period of dosage adjustment, increasing the frequency of medical check-ups may be necessary. You should not skip these visits even if you feel well. Your doctor will determine the frequency of control examinations.

To prevent any possible complications during treatment with Perindopril, you should also inform your doctor that you are taking Perindopril tablets:
- if you are to undergo anaesthesia and/or surgery (even at the dentist);
- if you are going to have treatment to reduce the effects of an allergy to bee or wasp stings (desensitisation);
- if you are to undergo hemodialysis or LDL cholesterol apheresis (which is removal of cholesterol from your body by a machine).

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

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

Do not take non-prescription medicines without consulting your doctor. This mainly applies to:
- cold remedies which contain pseudoephedrine or phenylephrine as active substances,
- pain relievers, including aspirin (a substance present in many medicines used to relieve pain and lower fever, as well as to prevent blood clotting);
- potassium supplements, and potassium-containing salt substitutes.

Please tell your doctor if you are taking any of the following to be sure that it is safe to take Perindopril at the same time:
- other medicines for treating high blood pressure and/or heart failure, including medicines that increase the amount of urine (diuretics);
- vasodilators including nitrates (products that make the blood vessels become wider);
- potassium-sparing diuretics (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 blood clots, trimethoprim and co-trimoxazole also known as trimethoprim/sulfamethoxazole, for infections caused by bacteria; ciclosporin or tacrolimus, immunosuppressant medicine used to prevent organ transplant rejection);
- potassium-sparing drugs used in the treatment of heart failure: eplerenone and spironolactone at doses between 12.5 mg to 50 mg per day;
- medicines for treatment of irregular heartbeat (procainamide);
- medicines for treatment of diabetes (insulin or oral antidiabetics, such as vildagliptin);
- baclofen (used to treat muscle stiffness in diseases such as multiple sclerosis);
- medicines for treatment of gout (allopurinol);
- non-steroidal anti-inflammatory drugs (NSAIDs such as ibuprofen, diclofenac), including acetylsalicylic acid for pain;
- estramustine (used in cancer therapy);
- medicines with a stimulant action on a certain part of the nervous system such as ephedrine, noradrenaline or adrenaline (sympathomimetics);
- medicines for treatment of mania or depression (lithium);
- medicines for mental illness such as depression, anxiety, schizophrenia or other psychosis (tricyclic antidepressants and antipsychotics);
- gold by injection for treatment of arthritis (sodium aurothiomalate);
- 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".

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 Perindopril" and "Warnings and precautions").

Perindopril with food, drink and alcohol

It is recommended that Perindopril should be taken before a meal in order to reduce the influence of food on the way in which the medicine works. Drinking alcohol with Perindopril may make you feel dizzy or light-headed. You should check with your doctor whether drinking is advisable for you.

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

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Article No.: xxxxxx
Article name.: xx PL PERINDOPRIL TBL 8 MG GB
Dimension: 148 ± 0,5 mm x 520 ± 0,8 mm
Material: Woodfree paper 50 g/m²
PhC No.: xxx
Measure: 1:1
Date: 09.09.2021
Prepared by: A. Mohorič
Checked by: N. Regina
Packaging Design

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direction of reading PhC

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Breastfeeding
Tell your doctor if you are breast-feeding or about to start breast-feeding. Perindopril 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
You are advised not to drive a car or operate machinery until you know how Perindopril affects you. Perindopril usually does not affect alertness but dizziness or weakness due to low blood pressure may occur in some patients, particularly at the start of treatment or in combination with another antihypertensive medication.
As a result the ability to drive or operate machinery may be impaired.

Perindopril contains lactose monohydrate and sodium
If you have been told by your doctor that you have an intolerance to some sugars, 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

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

The recommended starting and maintenance dose for the treatment of high blood pressure is 4 mg perindopril (1 Perindopril 4 mg tablet) once daily. When necessary, after one month this dose may be increased to 8 mg perindopril (2 Perindopril 4 mg tablets) once daily.

The recommended dose for the treatment of symptomatic heart failure is 2 mg perindopril (half of Perindopril 4 mg tablet or 1 Perindopril 2 mg tablet, if available) once daily; this may be increased to 4 mg perindopril (1 Perindopril 4 mg tablet or 2 Perindopril 2 mg tablets, if available) once daily, as necessary.

The recommended starting dose for the treatment of stable coronary artery disease is 4 mg perindopril (1 Perindopril 4 mg tablet) once daily; if it is well tolerated the dose may be increased to 8 mg perindopril (2 Perindopril 4 mg tablets) once daily.

Take your tablet with a glass of water, preferably at the same time each day, in the morning, before a meal.

During the course of treatment, your doctor will adjust the dosage according to the effect of treatment, as well as to your needs.

Kidney problems
Your doctor may prescribe a lower dose.

Liver problems
No dosage adjustment is necessary

Elderly
The dose recommendation in the elderly is depending on renal function.

Your doctor will determine the duration of treatment on the basis of your medical condition.

Use in children and adolescents
Efficacy and safety of perindopril use in children and adolescents under the age of 18 has not been established. Therefore, use in children and adolescents is not recommended.

If you have the impression that the effect of this medicine is too strong or too weak, consult your doctor or pharmacist.

If you take more Perindopril than you should
If you have taken too many tablets, consult with your doctor or pharmacist immediately.

The most likely sign of overdosage is a sudden drop in blood pressure (hypotension). Other symptoms may include fast or slow heartbeat (tachy- or bradycardia), unpleasant sensation of irregular and/or forceful heartbeat (palpitations), excessive rate and depth of respiration, dizziness, anxiety and/or cough.

If your blood pressure decreases substantially, you should lie down, prop up your lower extremities, and use only a small pillow as headrest.

If you forget to take Perindopril
It is important to take your medicine every day. However, if you forget to take one dose, just carry on with the next one as normal. Do not take a double dose to make up for forgotten individual dose. If you forget to take more than one dose, take another as soon as you remember and then go on as prescribed by your doctor.

If you stop taking Perindopril
Upon discontinuation of treatment, your blood pressure may increase again and this can increase the risk of hypertensive complications due to high blood pressure, especially in the heart, brain and kidneys. The condition of patients with heart failure may worsen inasmuch as to warrant hospitalization. Therefore, if you consider to stop taking Perindopril, you should discuss this with your doctor first.

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:
- swelling of the face, lips, mouth, tongue or throat, difficulty in breathing (angioedema) (See section 2 "Warnings and precautions") (Uncommon - may affect up to 1 in 100 people);
- severe dizziness or fainting due to low blood pressure (Common - may affect up to 1 in 10 people);
- unusual fast or irregular heart beat, chest pain (angina) or heart attack (Very rare - may affect up to 1 in 10,000 people);
- weakness of arms or legs, or problems speaking which could be sign of a possible stroke (Very rare - may affect up to 1 in 10,000 people);
- sudden wheeziness, chest pain, shortness of breath, or difficulty in breathing (bronchospasm) (Uncommon - may affect up to 1 in 100 people);
- inflamed pancreas which may cause severe abdominal and back pain accompanied with feeling very unwell (Very rare - may affect up to 1 in 10,000 people);
- yellowing of the skin or eyes (jaundice) which could be a sign of hepatitis (Very rare - may affect up to 1 in 10,000 people);
- skin rash which often starts with red itchy patches on your face, arms or legs (erythema multiforme) (Very rare - may affect up to 1 in 10,000 people).

The adverse reactions were categorized according to incidence, as follows:

Common (may affect up to 1 in 10 people):
- headache;
- dizziness;
- vertigo;
- pins and needles;
- vision disturbance;
- tinnitus (sensation of noises in the ears);
- cough;
- shortness of breath (dyspnoea);
- gastrointestinal 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;
- depression;
- 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.

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;
- 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.

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 via Yellow Card Scheme, Website: 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

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.

Do not store above 30 °C.
Store in the original package.

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 contains
- The active substance is perindopril tert-butylamine.

Perindopril 2 mg tablets:
Each tablet contains 2 mg perindopril tert-butylamine salt, equivalent to 1.669 mg perindopril.
Perindopril 4 mg tablets:
Each tablet contains 4 mg perindopril tert-butylamine salt, equivalent to 3.338 mg perindopril.
- The other ingredients are lactose monohydrate, microcrystalline cellulose, sodium hydrogen carbonate, colloidal anhydrous silica, magnesium stearate. See section 2 "Perindopril contains lactose monohydrate and sodium".

What Perindopril looks like and contents of the pack

Perindopril 2 mg tablets: tablets are white, round, biconvex tablets with bevelled edges.
Perindopril 4 mg tablets: tablets are white, oblong, biconvex tablets with bevelled edges and scored on one side. The tablet can be divided into equal doses.

Perindopril tablets are available in boxes of 7, 14, 28, 30, 50, 60, 90 or 100 tablets in blisters pack.
Not all pack sizes may be marketed.

Marketing Authorisation Holder
KRKA, d.d., Novo mesto, Šmarješka cesta 6,
8501 Novo mesto, Slovenia

Manufacturers:
KRKA Polska Sp. z o.o, ul. Równoległa 5, 02-235 Warsaw, Poland
or
KRKA, d.d., Novo mesto, Šmarješka cesta 6,
8501 Novo mesto, Slovenia
or
TAD Pharma GmbH, Heinz-Lohmann- Straße 5,
27472 Cuxhaven, Germany

This leaflet was last revised in 09/2021.

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