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.

Possible side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects that may need medical attention.

Breast-feeding

Do not start breast-feeding while you are taking Perindopril Tablets as it reduces the amount of milk produced by the breast. You should wait for at least 2 weeks after stopping Perindopril Tablets before you start breast-feeding. Perindopril Tablets is not recommended in early pregnancy, and must not be taken if you are more than 3 months pregnant. (It is preferable to take Perindopril Tablets in the 1st trimester of pregnancy; do not start taking this medicine because it contains an “angiotensin II receptor blocker” (ARB) if you are planning to become pregnant or as soon as you know you are pregnant.)

Tell your doctor if you are breast-feeding or about to become breast-feeding before starting Perindopril Tablets. If you become breast-feeding, or as soon as you know you are going to become breast-feeding, stop taking Perindopril Tablets immediately and see a doctor immediately. See also section 4.

Pregnancy

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

Tell your doctor if you think that 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 if you are more than 3 months pregnant, as it may cause serious harm to your baby.

Breast-feeding

Tell your doctor or pharmacist if you are breastfeeding or are about to start breastfeeding. Perindopril Tablets is not recommended in breastfeeding mothers. Breastfeeding mothers must not start taking Perindopril Tablets because it reduces the amount of milk produced by the breast. You should wait for at least 2 weeks after stopping Perindopril Tablets before you start breastfeeding. Perindopril Tablets contains lactose. If you have lactose intolerance or are breast-feeding, talk to your doctor before taking it.

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Possible side effects

Common (may affect up to 1 in 10 people):
- arthralgia (joint pain),
- photosensitivity reaction (increased sensitivity to sun),
- vasculitis (inflammation of blood vessels),
- tachycardia,
- palpitations,
- excess of eosinophils (a type of white blood cell),
- sweating,
- impotence,
- formation of blister clusters over the skin,
- intense itching or severe skin rashes,
- dry mouth,
- sleep disturbances,
- mood swings,
- muscle cramps,
- allergic reactions (such as skin rashes, itching),
- shortness of breath (dyspnoea),
- tinnitus (sensation of noises in the ears),
- vision disturbances,
- vertigo,
- headache.

Common (may affect up to 1 in 10 people):
- skin rash which often starts with red itchy areas,
- inflamed pancreas which may cause severe abdominal and back pain accompanied with vomiting,
- Very rare (may affect up to 1 in 10,000 people):
- swelling of the face, lips, mouth, tongue or throat,
- severe dizziness or fainting due to low blood pressure.

Tell your doctor if you notice any of the following side effects:
Common (may affect up to 1 in 10 people):
- severe dizziness or fainting due to low blood pressure.
- swelling of the face, lips, mouth, tongue or throat,
- unusual fast or irregular heartbeat, chest pain
- stroke,
- change in blood values such as a lower level of liver enzymes, high level of serum creatinine.
- changes in laboratory parameters: Increased level of potassium reversible on discontinuation.

Swallow your tablet with a glass of water, preferably at the same time each day, in the morning or before a meal. Your doctor will decide on the correct dose for you. The recommended dose is as follows:

High blood pressure: the usual starting dose is 2 mg once a day and after a further week to 4 mg once a day. After a week this can be increased to 4 mg once a day and then if necessary to 8 mg once a day.

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.

If you forget to take Perindopril Tablets

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:

If you stop taking the medicinal product after at least one month of regular treatment, the most likely effect is the reverse of the immediate effect (see details below). By reporting side effects directly (see below). By reporting side effects you can help provide more information on the safety of this medicine.

Keep this medicine out of the sight of children.

Store the original package in order to protect from light.

Do not store above 25°C.

Please read these leaflet before 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 is the last day of the month.

Do not throw 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-butyramine.

The active substance is perindopril tert-butyramine, equivalent to 6.676 mg perindopril. The tablets contain 8 mg of the active substance: perindopril tert-butyramine.

The other ingredients are:
- Lactose anhydrous,
- Albumin, gelatin (E407), colourant white ferric oxide (E172), magnesium stearate (E460) and magnesium silicate (E572).

What Perindopril Tablets looks like and contains of the pack

Tablet

Perindopril Tablets 8 mg tablets are white or off-white, rounded oval, uncoated tablets with a diameter of 12 mm on one side and “D” or “9” on either side of the break line on another side. The tablets contain 8 mg of the active substance.

Perindopril Tablets are available in blister packs of 28 or 30 tablets. Do not swallow desiccant.

All tablets are protected by an aluminium foil blister pack.

Marketing Authorisation Holder

MPH Pharma GmbH

Area Block, Odyssey Business Park

West End Business Park

Ruislip HA4 6QD

United Kingdom

Ares Block, Odyssey Business Park

Birzebbugia, BBG 3000.

Malta

Doctor Chart

Manufacturer

APL Swift Services (Malta) Limited

HFP, Hat Far Industril street, Hat Far, Birzebbuga, BP 330, Malta.

This medicinal product is authorised in the Member States of the EEA under the following names:

France: Perindopril Arrow Lab 8 mg,

comprise salicylic acid, etodolac 75 mg,

the Netherlands: Perindopril-Aurobindo 8 mg Tablets

Poland: Perindopril Astarnox 8 mg Tablets

United Kingdom: Perindopril 8 mg tablets

This leaflet was last revised in 03/2019.

How to take Perindopril Tablets

Always take this medicine exactly as your doctor or pharmacist has prescribed. Do not take more or less of the medicine than prescribed by your doctor or pharmacist if you are not sure.

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 once daily. 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 a day.

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 is the reverse of the immediate effect (see details below). By reporting side effects directly (see below). By reporting side effects you can help provide more information on the safety of this medicine.

The recommended dosages are as follows:

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 then if necessary to 8 mg once a day.

Stable coronary artery disease: the usual starting dose is 2 mg once a day and after a further week to 4 mg once a day.

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