

Package leaflet: Information for the patient

Perindopril Servier 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, pharmacist or nurse.
- 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 of the side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

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

Perindopril Servier 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 Servier 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 Servier

Do not take Perindopril Servier

- if you are allergic to perindopril, 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 Servier in early pregnancy – see pregnancy section.)
- if you have diabetes mellitus or kidney problems and you are treated with aliskiren.

Warning and precaution

If any of the following apply to you please talk to your doctor or pharmacist or nurse before taking Perindopril Servier:

- 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 suffer from a collagen 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 allergic to lactose; if you have or think you have problems in absorbing sugars (eg glucose, lactose, galactose) you should not take these tablets and should talk to your doctor. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.
- if you are to undergo anaesthesia and/or 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 take aliskiren (medicines used to treat hypertension).

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

Children and adolescents

Perindopril Servier is not recommended for use in children and adolescents.

Other medicines and Perindopril Servier

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

Treatment with Perindopril Servier can be affected by other medicines. These include:

- other medicines for treating high blood pressure including aliskiren, diuretics (water tablets, medicines that increase the amount of urine produced by the kidneys);
- potassium-sparing drugs (eg triamterene or amiloride); potassium supplements and potassium-containing salt substitutes;
- potassium-sparing drugs used in the treatment of heart failure : eplerenone and spironolacton at doses between 12.5 mg to 50 mg by day.
- medicines for the treatment of diabetes (such as insulin or metaformine) to lower blood sugar;
- lithium for mania or depression;
- baclofen (used to treat muscle stiffness in diseases such as multiple sclerosis).
- medicines for the treatment of mental disorders such as depression, anxiety, schizophrenia or other psychoses (e.g. tricyclic antidepressants, antipsychotics);
- trimethoprim (for the treatment of infections);
- estramustine (used in cancer therapy);
- 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);
- procainamide, a treatment for irregular heartbeat;
- non-steroidal anti-inflammatory drugs (NSAIDs, e.g. ibuprofen) for pain relief, including aspirin;
- medicines used for the treatment of low blood pressure, shock or asthma (eg ephedrine, noradrenaline or adrenaline);

- vasodilators including nitrates (products that make the blood vessels become wider);
- heparin (used to thin the blood);
- gold salts, especially with intravenous administration (used to treat symptoms of rheumatoid arthritis).

Taking Perindopril Servier with food and drink

It is preferable to take Perindopril Servier before a meal.

Pregnancy and Breast-feeding

If you are pregnant or breastfeeding, 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 that you are (or might become) pregnant. Your doctor will normally advise you to stop taking Perindopril Servier before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Perindopril Servier. Perindopril Servier 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 Servier 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 Servier 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 Servier contains 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 Servier

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 are as follows:

High blood pressure: the usual starting and maintenance dose for treatment in adults is 4 mg once a day. 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 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 month, 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 Servier 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 Servier

It is important to take your medicine every day as regular treatment works better. However, if you forget to take a dose of Perindopril Servier 8mg, 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 Servier

As the treatment with Perindopril Servier 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 product, 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:

- swelling of the face, lips, mouth, tongue or throat, difficulty in breathing,
- severe dizziness or fainting,
- unusual fast or irregular heart beat or chest pain,
- severe abdominal pain.

In decreasing order of frequency, side effects can include:

- 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, 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, bronchospasm (tightening of the chest, wheezing and shortness of breath), dry mouth, angioedema (symptoms such as wheezing, swelling of the face, tongue or throat), intense itching or severe skin rashes, formation of blister clusters over the skin, kidney problems, impotence, sweating, an 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,

- Very rare (may affect up to 1 in 10,000 people): confusion, cardiovascular disorders (irregular heartbeat, heart attack and stroke), eosinophilic pneumonia (a rare type of pneumonia), rhinitis (blocked up or runny nose), erythema multiforme, 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, inflammation of the pancreas (which causes severe pain in the abdomen and the back), hepatitis.

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 HPRAs
Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517.
Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Perindopril Servier

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 blister. The expiry date refers to the last day of that month.

Do not store above 30° C.

Do not throw away any medicine via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Content of the pack and other information

What Perindopril Servier 8 mg contains

- The active substance is perindopril tert-butylamine. One tablet contains 6.676 mg perindopril (corresponding to 8 mg perindopril tert-butylamine).
- The other ingredients are: microcrystalline cellulose, lactose monohydrate, colloidal anhydrous silica, magnesium stearate.

What Perindopril Servier 8 mg looks like and contents of the pack

Perindopril Servier 8 mg tablets are white, round convex tablets.

The tablets are available in blister packs (PVC/Aluminium) of 30.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder :

Les Laboratoires Servier
50, rue Carnot
92284 Suresnes cedex – France

Manufacturer:

Servier (Ireland) Industries Ltd
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