



Length: 500 mm
Width: 120 mm
Depth: -

Colours Used:

PANTONE® GREEN C

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Template

Perindopril tosilate Teva 5 mg film-coated tablets
Perindopril tosilate Teva 10 mg film-coated tablets
perindopril tosilate

Package leaflet: Information for the user

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

1 What Perindopril tosilate Teva is and what it is used for

Perindopril tosilate 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 tosilate Teva is used:

- to treat *high blood pressure* (hypertension),
- [5 mg strengths] 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 vessels that supply it.

2 What you need to know before you take Perindopril tosilate Teva

Do not take Perindopril tosilate Teva

- if you are allergic to perindopril, to any other ACE inhibitor or 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 tosilate Teva in early pregnancy – see section 2: Pregnancy, breast-feeding and fertility),
- 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.

Warnings and precautions

Talk to your doctor or pharmacist before taking Perindopril tosilate Teva if any of the following apply:

- if you are taking any of the following medicines, the risk of angioedema may be 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.
- 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 problems,
- if you have liver problems,
- if you have kidney problems or if you are receiving dialysis,
- if you suffer from a collagen vascular disease (disease of the connective tissue) such as systemic lupus erythematosus or scleroderma,
- if you have diabetes,
- if you are on a salt restricted diet or use salt substitutes which contain potassium,
- 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 have recently suffered from diarrhoea or vomiting, or are dehydrated,

- if you have been told by your doctor that you have an intolerance to some sugars,
- 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 tosilate Teva'.

You must tell your doctor if you think that you are (or might become) pregnant. Perindopril tosilate Teva 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 section 2: Pregnancy, breast-feeding and fertility).

Children and adolescents

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

Other medicines and Perindopril tosilate Teva

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

Treatment with Perindopril tosilate Teva 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 high blood pressure, including diuretics (medicines which increase the amount of urine produced by the kidneys),
- 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 tosilate Teva' and 'Warnings and precautions')
- 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)
- lithium for mania or depression,
- non-steroidal anti-inflammatory drugs (e.g. ibuprofen) for pain relief or high dose aspirin,
- medicines to treat diabetes (such as insulin or metformin),
- medicines to treat mental disorders such as depression, anxiety, schizophrenia etc (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),
- allopurinol (for the treatment of gout),
- procainamide (for the treatment of an irregular heart beat),
- vasodilators including nitrates (products that make the blood vessels become wider),
- medicines used for the treatment of low blood pressure, shock or asthma (e.g. ephedrine, noradrenaline or adrenaline),
- medicines, which are 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'.

Perindopril tosilate Teva with food and drink

It is preferable to take Perindopril tosilate Teva 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 that you are (or might become) pregnant. Your doctor will normally advise you to stop taking Perindopril tosilate Teva before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Perindopril tosilate Teva. Perindopril tosilate Teva 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 tosilate Teva 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.

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UK & Ireland Artwork Department

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Fertility

Effects on fertility by perindopril in humans are not known.

Driving and using machines

Perindopril tosilateTeva 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 tosilate Teva 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.

Perindopril tosilate Teva contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3 How to take Perindopril tosilate Teva

Always take this medicine exactly as your doctor 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 recommended starting and maintenance dose is 5 mg once daily. After one month, this can be increased to 10 mg once a day if required. 10 mg a day is the maximum recommended dose for high blood pressure.

If you are 65 or older, the recommended starting dose is 2.5 mg once a day. After a month this can be increased to 5 mg once a day and then if necessary to 10 mg once daily.

[2.5 mg and 5 mg strengths] *Heart failure:* the recommended starting dose is 2.5 mg once daily. After two weeks, this can be increased to 5 mg once a day, which is the maximum recommended dose for heart failure.

Stable coronary artery disease: the recommended starting dose is 5 mg once daily. After two weeks, this can be increased to 10 mg once daily, which is the maximum recommended dose in this indication.

If you are 65 or older, the recommended starting dose is 2.5 mg once a day. After a week this can be increased to 5 mg once a day and after a further week to 10 mg once daily.

If you take more Perindopril tosilate Teva 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.

If you forget to take Perindopril tosilate Teva

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

As the treatment with Perindopril tosilateTeva 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.

If you experience any of the following, stop taking the medicinal product at once and tell your doctor immediately:

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

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, 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 tiredness,
- 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), kidney problems, impotence, sweating,
- Rare (may affect up to 1 in 1,000 people): psoriasis worsening,
- Very rare (may affect up to 1 in 10,000 people): confusion, cardiovascular disorders (irregular heart beat, angina, heart attack and stroke), eosinophilic pneumonia (a rare type of pneumonia), rhinitis (blocked up or runny nose), erythema multiforme, disorders of the blood, pancreas or liver,

- Not known (frequency cannot be estimated from available data): Discoloration, numbness and pain in fingers or toes (Raynaud's phenomenon),
- In case of diabetic patients, hypoglycaemia (very low blood sugar level) can occur,
- Vasculitis (inflammation of blood vessels) have been reported.

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 HPRA Pharmacovigilance Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Perindopril tosilate Teva

Keep this medicine out of the sight and reach of children. Once opened, use within 100 days. Do not use this medicine after the expiry date which is stated on the carton and bottle after EXP. The expiry date refers to the last day of that month.

Keep the container tightly closed in order to protect from light and moisture. This medicine does not require any special temperature storage conditions.

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 tosilate Teva contains

- The active substance is perindopril tosilate. Each film-coated tablet contains 1.704 mg perindopril (corresponding to 2.5 mg perindopril tosilate), or 3.408 mg perindopril (corresponding to 5 mg perindopril tosilate), or 6.816 mg perindopril (corresponding to 10 mg perindopril tosilate).
- The other ingredients are lactose monohydrate, maize starch, sodium hydrogen carbonate, pregelatinized starch, povidone K30, magnesium stearate, Poly(vinyl alcohol) - part hydrolyzed, titanium dioxide E171, macrogol 3350, talc and for the 5 mg and 10 mg tablets indigo carmine E132, brilliant blue FCF E133, iron oxide yellow E172 and quinoline yellow E104.

What Perindopril tosilate Teva looks like and contents of the pack

Perindopril tosilateTeva 2.5 mg tablets are white, round, biconvex, film-coated tablets of approx. 5 mm diameter, debossed "T" on one side and plain on the other.

Perindopril tosilateTeva 5 mg tablets are light-green, capsule-shaped, biconvex film-coated tablets of approx. 4 mm width and 8 mm length, debossed "T" on one side, plain on the other side with breaklines on both edges.

Perindopril tosilateTeva 10 mg tablets are green, round, biconvex, film-coated tablets of approx. 8 mm diameter, debossed "10" on one side and "T" on the other.

5 mg: The tablets are available in containers of 10, 30, 60, 90, 90 (3x30), 100 or 120 (2x60) film-coated tablets.

2.5 mg, 10 mg: The tablets are available in containers of 30, 60, 90, 90 (3x30), 100 or 120 (2x60) film-coated tablets

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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

Bulgaria:	Zaprinel
Estonia:	Perindopril Teva
Greece:	Perindopril Teva Pharma
France:	Perindopril tosilate Teva
Hungary:	Perindopril-tozilát Teva
Ireland:	Perindopril tosilate Teva
Italy:	Perindopril Teva Italia
Lithuania:	Perindopril Teva
Latvia:	Perindopril Teva
The Netherlands:	Perindopril tosilat 5mg/10mg Teva
Poland:	Perindoprilum 123ratio
Portugal:	Perindopril Rytulop
Romania:	Perindopril tosilat Teva
Slovenia:	Perivol filmsko obložene tablete

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