

Package leaflet: Information for the user

Perindopril Tosilate/Amlodipine Teva B.V. 5 mg/5 mg tablets
Perindopril Tosilate/Amlodipine Teva B.V. 5 mg/10 mg tablets
Perindopril Tosilate/Amlodipine Teva B.V. 10 mg/5 mg tablets
Perindopril Tosilate/Amlodipine Teva B.V. 10 mg/10 mg tablets

perindopril tosilate/amlodipine

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

1. What Perindopril Tosilate/Amlodipine Teva B.V. is and what it is used for

Perindopril Tosilate/Amlodipine Teva B.V. is a combination of two active ingredients, perindopril and amlodipine.

Perindopril Tosilate/Amlodipine Teva B.V. **5 mg/5 mg tablets** contains 5 mg of perindopril tosilate and 5 mg of amlodipine.

Perindopril Tosilate/Amlodipine Teva B.V. **5 mg/10 mg tablets** contains 5 mg of perindopril tosilate and 10 mg of amlodipine.

Perindopril Tosilate/Amlodipine Teva B.V. **10 mg/5 mg tablets** contains 10 mg of perindopril tosilate and 5 mg of amlodipine

Perindopril Tosilate/Amlodipine Teva B.V. **10 mg/10 mg tablets** contains 10 mg of perindopril tosilate and 10 mg of amlodipine

Perindopril Tosilate/Amlodipine Teva B.V. is prescribed for treatment of high blood pressure (hypertension) and/or treatment of stable coronary artery disease (a condition where the blood supply to the heart is reduced or blocked).

Patients already taking perindopril and amlodipine tablets separately may instead receive one tablet of Perindopril Tosilate/Amlodipine Teva B.V. which contains both ingredients.

Perindopril is an ACE (angiotensin converting enzyme) inhibitor. Amlodipine is a calcium antagonist (which belongs to a class of medicines called dihydropyridines). Together they work to widen and relax the blood vessels so that blood passes through them more easily and makes it easier for your heart to maintain a good blood flow.

2. What you need to know before you take Perindopril Tosilate/Amlodipine Teva B.V.

Do not take Perindopril Tosilate/Amlodipine Teva B.V. if you

- are allergic to perindopril or any other ACE inhibitor, or to amlodipine or any other calcium channel antagonists, or any of the other ingredients of this medicine (listed in section 6).
- are more than 3 months pregnant (it is also better to avoid Perindopril Tosilate/Amlodipine Teva B.V. in early pregnancy – see section 2: Pregnancy and breastfeeding).
- have experienced symptoms such as wheezing, swelling of the face or tongue, severe itching or severe skin rashes with previous ACE inhibitor treatment or if you or a member of your family has had these symptoms in any other circumstances (a condition called angioedema).
- have narrowing of the aortic heart valve (aortic stenosis)
- have cardiogenic shock (a condition where your heart is unable to supply enough blood to the body).
- have severe low blood pressure (hypotension).
- suffer from heart failure after a heart attack.
- have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.
- 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.
- are on dialysis or if you are receiving another type of blood filtration. Depending on the machine used, Perindopril Tosilate/Amlodipine Teva B.V. may not be suitable.
- have kidney problems with decreased blood supply to the kidneys (stenosis renal arterial).

Warnings and precautions

Talk to your doctor or pharmacist before taking Perindopril Tosilate/Amlodipine Teva B.V. if you have any of the following:

- Hypertrophic cardiomyopathy (cardiac muscle disease) or renal artery stenosis (narrowing of the artery which supplies the kidney with blood).
- Heart failure.
- Severe increase in blood pressure (hypertensive crisis).
- Any other heart problems.
- Liver problems.
- Kidney problems or if you are receiving dialysis.
- Have abnormally high levels of a hormone called aldosterone in your blood (primary aldosteronism).
- Collagen vascular disease (disease of the connective tissue) such as systemic lupus erythematosus or scleroderma.
- Diabetes.
- If you are on a salt restricted diet or use salt substitutes which contain potassium (a well balanced potassium blood level is essential).
- If you are elderly and your dose needs to be increased.
- If you are taking any of the following medicines, the risk of serious allergic reaction (angioedema) may be increased, racecadotril, mTOR inhibitors, vildagliptin, sacubitril, see **“Other medicines and Perindopril Tosilate/Amlodipine Teva B.V.”**.
- If you are a black patient, this medicine may increase the risk of serious allergic reaction (angioedema) and may be less effective on lowering your blood pressure compared to other patients.
- 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/Amlodipine Teva B.V.” remove

When you are taking Perindopril Tosilate/Amlodipine Teva B.V., you should also inform your doctor or the medical staff if you:

- Are going to have a general anaesthetic and/or major surgery.
- Have recently suffered from diarrhoea or vomiting.

- Are to undergo low density lipoprotein (LDL) apheresis (the removal of cholesterol from your blood by a machine).
- Are going to have desensitisation treatment to reduce the effects of an allergy to bee or wasp stings.

Children and adolescents

Perindopril Tosilate/Amlodipine Teva B.V. is not recommended for use in children and adolescents.

Other medicines and Perindopril Tosilate/Amlodipine Teva B.V.

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

You should avoid Perindopril Tosilate/Amlodipine Teva B.V. with:

- Lithium (used to treat mania or depression).
- Estramustine (used in certain types of cancer therapy).
- Potassium supplements (including salt substitutes), potassium-sparing diuretics (triamterene, amiloride) 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).
- Potassium-sparing drugs used in the treatment of heart failure: eplerenone and spironolactone at doses between 12.5 mg and 50 mg per day.

Treatment with Perindopril Tosilate/Amlodipine Teva B.V. can be affected by other medicines. Make sure to tell your doctor if you are taking any of the following medicines as special care may be required:

- Medicines which are most often used to treat diarrhoea (racecadotril) or avoid rejection of transplanted organs (sirolimus, everolimus, temsirolimus and other drugs belonging to the class of so-called mTor inhibitors, tacrolimus and vildagliptin) as they may increase risk of serious allergic reaction.
- Other medicines for high blood pressure, including angiotensin II receptor blocker (ARBs also known as sartans for example, valsartan, telmisartan, irbesartan), aliskiren or diuretics (medicines which increase the amount of urine produced by the kidneys).
- Non-steroidal anti-inflammatory drugs (e.g. ibuprofen) for pain relief or high dose aspirin (acetyl salicylic acid).
- Medicines to treat diabetes (such as insulin and vildagliptin).
- Medicines to treat mental disorders such as depression, anxiety, schizophrenia (e.g. tricyclic antidepressants, antipsychotics, imipramine-like antidepressants and neuroleptics).
- 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 and tacrolimus).
- Allopurinol (for the treatment of gout).
- Trimethoprim and co-trimoxazole (to treat infections).
- Procainamide (for the treatment of an irregular heartbeat).
- Vasodilators including nitrates (products that dilate blood vessels).
- Ephedrine, noradrenaline or adrenaline (medicines used to treat low blood pressure, shock or asthma).
- Baclofen or dantrolene (infusion) both used to treat muscle stiffness in diseases such as multiple sclerosis; dantrolene is also used to treat malignant hyperthermia during anaesthesia (symptoms including very high fever and muscle stiffness).
- Certain antibiotics used to treat bacterial infections such as rifampicin, erythromycin and clarithromycin.
- Antiepileptic agents such as carbamazepine, phenobarbital, phenytoin, fosphenytoin, primidone.
- Itraconazole, ketoconazole (medicines used for treatment of fungal infections).
- Alpha-blockers used for the treatment of enlarged prostate such as prazosin, alfuzosin, doxazosin, tamsulosin, terazosin.
- Amifostine (used to prevent or reduce side effects caused by other medicines or radiation therapy that are used to treat cancer).
- Corticosteroids (used to treat various conditions including severe asthma and rheumatoid arthritis).
- Gold salts, especially with intravenous administration (used to treat symptoms of rheumatoid arthritis).
- Ritonavir, indinavir, nelfinavir (so called protease inhibitors used to treat HIV).
- Simvastatin (used to lower cholesterol).

- Sacubitril (available in fixed-dose combination with valsartan) used to treat chronic heart failure.
- *Hypericum perforatum* (St John's wort, a herbal medicine used for treatment of depression).

Perindopril Tosilate/Amlodipine Teva B.V. with food and drink

It is advisable to take Perindopril Tosilate/Amlodipine Teva B.V. before a meal.

Grapefruit juice and grapefruit should not be consumed by people who are taking Perindopril Tosilate/Amlodipine Teva B.V.. This is because grapefruit and grapefruit juice can lead to an increase in the blood levels of the active ingredient amlodipine, which can cause an unpredictable increase in the blood pressure lowering effect of Perindopril Tosilate/Amlodipine Teva B.V..

Pregnancy and breastfeeding

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 you are (*or might become*) pregnant. Your doctor will normally advise you to stop taking Perindopril Tosilate/Amlodipine Teva B.V. 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/Amlodipine Teva B.V.. Perindopril Tosilate/Amlodipine Teva B.V. 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.

Breastfeeding

Amlodipine has been shown to pass into breast milk in small amounts. Tell your doctor if you are breastfeeding or about to start breastfeeding. Perindopril Tosilate/Amlodipine Teva B.V. is not recommended for mothers who are breastfeeding, and your doctor may choose another treatment for you if you wish to breastfeed, especially if your baby is newborn, or was born prematurely.

Driving and using machines

Perindopril Tosilate/Amlodipine Teva B.V. may affect your ability to drive and use machines. If the tablets make you feel sick, dizzy, weak or tired, or give you a headache, do not drive or use machines and contact your doctor **immediately**.

Perindopril Tosilate/Amlodipine Teva B.V. contains sodium

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

Perindopril Tosilate/Amlodipine Teva B.V. contains isomalt

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 Tosilate/Amlodipine Teva B.V.

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 appropriate dosage for you. This will normally be one tablet per day.

Perindopril Tosilate/Amlodipine Teva B.V. will usually be prescribed for patients already taking perindopril and amlodipine tablets separately.

If you take more Perindopril Tosilate/Amlodipine Teva B.V. than you should

If you have taken too many tablets, contact the nearest accident and emergency department at the nearest hospital 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 your legs raised can help.

Excess fluid may accumulate in your lungs (pulmonary oedema) causing shortness of breath that may develop up to 24-48 hours after intake.

If you forget to take Perindopril Tosilate/Amlodipine Teva B.V.

It is important to take your medicine every day as regular treatment is more effective. However, if you forget to take a dose of Perindopril Tosilate/Amlodipine Teva B.V., take the next dose the next day as usual. Do not take a double dose to make up for a forgotten dose.

If you stop taking Perindopril Tosilate/Amlodipine Teva B.V.

As the treatment with Perindopril Tosilate/Amlodipine Teva B.V. is usually long-term, you should discuss with your doctor before you stop taking your tablets.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist for more information.

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**:

Common side effects (may affect up to 1 in 10 people):

- Severe dizziness or fainting due to low blood pressure

Uncommon side effects (may affect up to 1 in 100 people):

- Sudden wheezing, chest pain, shortness of breath or difficulty in breathing
- Swelling of the eyelids, face or mouth
- Swelling of the lips, tongue and throat, causing great difficulty in breathing
- Depression

Very rare side effects (may affect 1 in 10,000 people):

- Severe skin reactions, including severe skin rash, hives, redness of the skin on whole body, severe itching, blistering, peeling and swelling skin, inflammation of the mucous membranes (Steven-Johnson syndrome, epidermal necrolysis) or to other allergic reactions
- Weakness of arms or legs, or problems speaking which could be a sign of a possible stroke
- Unusual fast or irregular heart beat, chest pain (angina) or heart attack
- Inflammation of the pancreas may cause severe abdominal and dorsal pain accompanied by a great feel of discomfort
- Yellowing of the skin or eyes (jaundice) which could be a sign of hepatitis

The following **common side effects** have been reported. If **any of these effects** cause you problems or if they **last for more than one week**, you should **contact your doctor**.

- Very common side effects (may occur in more than 1 use in 10): oedema (water retention)
- Common side effects (may affect up to 1 in 10 people): headache, dizziness, drowsiness (especially at the beginning of treatment), vertigo, numbness or tingling sensation in your limbs, vision disturbances (including double vision), sensation of noises in the ears (tinnitus), awareness of your heartbeat (palpitations), flushing, light-headedness due to low blood pressure, cough, shortness of breath, nausea (feeling sick), vomiting (being sick), abdominal pain, taste disturbances, dyspepsia or difficulty of digestion, diarrhoea, constipation, allergic reactions (such as skin rashes, itching), muscle cramps, tiredness, weakness, ankle swelling (peripheral oedema).

Other side effects listed below have also been reported. If you feel any of the effects listed as serious or if you experience any side effects not listed, please inform your doctor or pharmacist.

- Uncommon side effects (may affect up to 1 in 100 people): mood swings, anxiety, depression, sleeplessness, sleep disturbances, tremor, loss of consciousness, loss of pain sensation, inflamed or blocked nose (rhinitis), irregular heartbeat, altered bowel habits, hair loss, red patches on skin, skin discoloration, back pain, muscle or joint pain, chest pain, difficulty in passing urine, increased urination, pain, feeling unwell, bronchospasm (feeling tightness in the chest, noisy and short breathing), dry mouth, wheezing, swelling of the face and tongue (angioedema), blistering of skin, kidney problems, impotence, increased sweating, discomfort or enlargement of the breasts in men, weight increase or decrease, excess of eosinophils (a type of white blood cell), intense itching or severe skin rashes, tachycardia, fever, fall, fainting, faster heart beat, inflammation of blood vessels (vasculitis), photosensitivity reaction (increased sensitivity of the skin to sun), malaise, change in biological 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 level.
- Rare side effects (may affect up to 1 in 1,000 people): confusion, psoriasis worsening, changes in biological 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 and acute renal failure.
- Very rare side effects (may affect up to 1 in 10,000 people): cardiovascular disorders (angina pectoris, heart attack and stroke), pneumonia eosinophilic (a rare form of pneumonia), swelling of the eyelids, face or lips, swelling of the tongue and throat resulting in severe breathing difficulties, severe skin rashes including intense skin rash, hives, redness of the skin on the whole body, severe itching, appearance of vesicles, peeling and swelling of the skin, inflammation of the mucous membranes (Stevens-Johnson syndrome), rash dermal often starting with red spots and itching on the face, arms or legs (erythema multiforme), sensitivity to light, changes in blood constants such as decreased the number of white and red blood cells, a decrease in haemoglobin, a decrease in number of platelets, blood disorders, inflammation of the pancreas that can cause severe abdominal and dorsal pain with severe discomfort, abnormal liver function, liver inflammation (hepatitis), yellowing of the skin (jaundice), elevated liver enzymes that may affect some abdominal bloating (gastritis), nerve disorders resulting in weakness, tingling or numbness (increased muscle tension), swelling of gums, increased blood sugar (hyperglycaemia).
- Not known (frequency cannot be estimated from available data): Rigid posture, frozen facial expression, slow and sluggish movements, walking unbalanced, 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 HPRC 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/Amlodipine Teva B.V.

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 box and tablet container after EXP. The expiry date refers to the last day of that month.

This product does not require any special temperature storage conditions.

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

Keep the container tightly closed.

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/Amlodipine Teva B.V. contains

- The active substances are perindopril tosilate and amlodipine.
Each tablet contains 5 mg perindopril tosilate equivalent to 3.4 mg perindopril and 6.935 mg amlodipine besilate equivalent to 5 mg amlodipine.
Each tablet contains 5 mg perindopril tosilate equivalent to 3.4 mg perindopril and 13.87 mg amlodipine besilate equivalent to 10 mg amlodipine.
Each tablet contains 10 mg perindopril tosilate equivalent to 6.8 mg perindopril and 6.935 mg amlodipine besilate equivalent to 5 mg amlodipine.
Each tablet contains 10 mg perindopril tosilate equivalent to 6.8 mg perindopril and 13.87 mg amlodipine besilate equivalent to 10 mg amlodipine.
- The other ingredients are sodium hydrogen carbonate, povidone K30, isomalt, microcrystalline cellulose, sodium starch glycolate (type A), magnesium stearate.

What Perindopril Tosilate/Amlodipine Teva B.V. looks like and contents of the pack

Perindopril Tosilate/Amlodipine Teva B.V. 5 mg/5 mg tablets are white, oval, biconvex tablet, debossed "5/5" on one side and plain on the other side.

Perindopril Tosilate/Amlodipine Teva B.V. 5 mg/10 mg tablets are white, round, biconvex tablet, debossed "5/10" on one side and plain on the other side.

Perindopril Tosilate/Amlodipine Teva B.V. 10 mg/5 mg tablets are white, oval, biconvex tablet, debossed "10/5" on one side and plain on the other side.

Perindopril Tosilate/Amlodipine Teva B.V. 10 mg/10 mg tablets are white, round, biconvex tablet, debossed "10/10" on one side and plain on the other side.

Perindopril Tosilate/Amlodipine Teva B.V. stored in tablet containers (polypropylene (PP) with desiccant present in the lid) are available in pack sizes of:

5 mg/5 mg: 10, 30 and multipacks containing 90 (3 packs of 30) tablets.

5 mg/10 mg, 10 mg/5 mg & 10 mg/10 mg: 30 and multipacks containing 90 (3 packs of 30) tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Teva B.V.
Swensweg 5
2031GA Haarlem
The Netherlands

Manufacturer

TEVA Pharmaceutical Works Private Limited Company
Pallagi út 13
4042 Debrecen
Hungary

Teva Operations Poland Sp z.o.o
ul. Mogilska 80. 31-546
Krakow, Poland

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

Belgium Perindopril / Amlodipine tabletten, comprimés, Tabletten

Bulgaria	Zalpam tablets
Czech Republic	Perindopril tosilate/amlodipine Teva B.V.
Estonia	Perindopril/ Amlodipine Actavis
Hungary	Perindopril tosilat/amlodipin Pliva tablete
Ireland	Perindopril Tosilate/Amlodipine Teva B.V. tablets
Italy	PERINDOPRIL E AMLODIPINA TEVA ITALIA
Lithuania	Perindopril tosilate/ Amlodipine Teva Pharma tabletės
Latvia	Perindopril/Amlodipine Actavis tabletes
Netherlands	Perindopril tosilaat/Amlodipine Teva tabletten
Poland	Vilpin Combi
Portugal	Perindopril + Amlodipina Teva

This leaflet was last revised in June 2022