

Package leaflet: Information for the user

[invented name] 5 mg/5 mg Tablets
[invented name] 5 mg/10 mg Tablets
[invented name] 10 mg/5 mg Tablets
[invented name] 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 [invented name] is and what it is used for
2. What you need to know before you take [invented name]
3. How to take [invented name]
4. Possible side effects
5. How to store [invented name]
6. Contents of the pack and other information

1. What [invented name] is and what it is used for

[invented name] is a combination of two active ingredients, perindopril and amlodipine.

[invented name] **5 mg/5 mg Tablets** contains 5 mg of perindopril tosilate and 5 mg of amlodipine.

[invented name] **5 mg/10 mg Tablets** contains 5 mg of perindopril tosilate and 10 mg of amlodipine.

[invented name] **10 mg/5 mg Tablets** contains 10 mg of perindopril tosilate and 5 mg of amlodipine

[invented name] **10 mg/10 mg Tablets** contains 10 mg of perindopril tosilate and 10 mg of amlodipine

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.

[invented name] 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 from separate tablets may instead receive one tablet of [invented name] which contains both ingredients.

2. What you need to know before you take [invented name]

Do not take [invented name]

- If you are allergic to perindopril or any other ACE inhibitor, or to amlodipine or any other calcium antagonists, 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 [invented name] in early pregnancy – see section 2: Pregnancy and breast-feeding).

- If you have experienced symptoms such as wheezing, swelling of the face or tongue, 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 narrowing of the aortic heart valve (aortic stenosis) or cardiogenic shock (a condition where your heart is unable to supply enough blood to the body).
- If you have severe low blood pressure (hypotension).
- If you suffer from heart failure after a heart attack.
- 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 [invented name] 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.
- 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 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.
- 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.

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 [invented name]”

You must tell your doctor if you think you are (*or might become*) pregnant. [invented name] 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 and breast-feeding).

When you are taking [invented name], 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 (being sick).
- Are to undergo 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

[invented name] is not recommended for use in children and adolescents.

Other medicines and [invented name]

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

You should avoid [invented name] with:

- Lithium (used to treat mania or depression).
- Estramustine (used in cancer therapy).
- 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).

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 [invented name]” and “Warnings and precautions”)

Treatment with [invented name] 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:

- Other medicines for high blood pressure, including 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 acetyl salicylic acid.
- Medicines to treat diabetes (such as insulin).
- Medicines to treat mental disorders such as depression, anxiety, schizophrenia etc. (e.g. tricyclic antidepressants, antipsychotics, imipramine-like antidepressants, 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).
- Allopurinol (for the treatment of gout).
- Procainamide (for the treatment of an irregular heart beat).
- Vasodilators including nitrates (products that widen the 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).
- rifampicin, erythromycin, clarithromycin (antibiotics).
- 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).
- 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”.
- Tacrolimus (used to control your body’s immune response, enabling your body to accept the transplanted organ).

[invented name] with food and drink

Grapefruit juice and grapefruit should not be consumed by people who are taking [invented name]. 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 [invented name].

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 [invented name] before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of [invented name]. [invented name] 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

Amlodipin has been shown to pass into breast milk in small amounts. Tell your doctor if you are breast-feeding or about to start breast-feeding. [invented name] 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

[invented name] may affect your ability to drive or 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.

[invented name] 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.

[invented name] 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 [invented name]

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. This will normally be one tablet per day.

[invented name] will usually be prescribed for patients already taking perindopril and amlodipine from separate tablets.

If you take more [invented name] 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 your legs raised can help.

If you forget to take [invented name]

It is important to take your medicine every day as regular treatment works better. However, if you forget to take a dose of [invented name], 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 [invented name]

As the treatment with [invented name] is usually life-long, 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.

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 wheeziness, chest pain, shortness of breath, or difficulty in breathing.
- Swelling of eyelids, face or mouth.
- Swelling of the lips, tongue and throat, which causes great difficulty in breathing.

Very rare side effects (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.
- Severe skin reactions including intense skin rash, hives, reddening of the skin over your whole body, severe itching, blistering, peeling and swelling of the skin, inflammation of mucous membranes (Stevens Johnson Syndrome) or other allergic reactions.
- Unusual fast or irregular heart beat, chest pain(angina) or heart attack.
- Inflamed pancreas which may cause severe abdominal and back pain accompanied with feeling very unwell.
- Yellowing of the skin or eyes (jaundice) which could be a sign of hepatitis

Not known side effects (frequency cannot be estimated from the available data):

- Severe skin reactions including intense skin rash, hives, reddening of the skin over your whole body, severe itching, blistering, peeling and swelling of the skin, inflammation of mucous membranes (toxic epidermal necrolysis) or other allergic reactions

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

- Common side effects (may affect up to 1 in 10 people): headache, dizziness, sleepiness (especially at the beginning of treatment), vertigo, numbness or tingling sensation in your limbs, vision disturbances (including double vision), tinnitus (sensation of noises in the ears), palpitations (awareness of your heartbeat), 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 (oedema).
- Uncommon side effects (may affect up to 1 in 100 people): mood swings, anxiety, depression, sleeplessness, sleep disturbances, trembling, loss of pain sensation, rhinitis (blocked up or runny nose), altered bowel habits, hair loss, red patches on skin, skin discoloration, back pain, muscle or joint pain, chest pain, disorder in passing urine, increased need to urinate at night, increased number of times of passing urine, pain, feeling unwell, dry mouth, 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, formation of blister clusters over the skin, fever, fall, fainting, faster heart beat, vasculitis (inflammation of blood vessels), photosensitivity reaction (increased sensitivity of the skin to sun), malaise, 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 side effects (may affect up to 1 in 1,000 people): confusion, psoriasis worsening, changes in laboratory parameters: increased level of liver enzymes, high level of serum bilirubin.
- Very rare side effects (may affect up to 1 in 10,000 people): cardiovascular disorders (angina and stroke), eosinophilic pneumonia (a rare type of pneumonia), erythema multiforme (a skin rash which often starts with red itchy patches on your face, arms or legs), sensitivity to light, disorders of the blood, abnormal liver function, inflammation of the liver (hepatitis), yellowing of the skin (jaundice),

abdominal bloating (gastritis), disorder of the nerves which can cause weakness, tingling or numbness, increased muscle tension, swelling of the gums, excess sugar in blood (hyperglycaemia), 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.

- Not known (frequency cannot be estimated from available data): discoloration, numbness and pain in fingers or toes (Raynaud's phenomenon)
- The following side effects have also been reported by patients taking [invented name]: disorders combining rigidity, tremor, and/or movements disorders, trembling, rigid posture, mask-like face, slow movements and a shuffling, unbalanced walk.

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 the national reporting system listed in Appendix V*. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [invented name]

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 bottle after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special temperature storage conditions.

Keep the tablet container tightly closed in order to protect from light and moisture.

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 [invented name] contains

- The active substances are perindopril tosylate and amlodipine.
Each tablet contains 5 mg perindopril tosylate equivalent to 3.4 mg perindopril and 6.935 mg amlodipine besilate equivalent to 5 mg amlodipine.
Each tablet contains 5 mg perindopril tosylate equivalent to 3.4 mg perindopril and 13.87 mg amlodipine besilate equivalent to 10 mg amlodipine.
Each tablet contains 10 mg perindopril tosylate equivalent to 6.8 mg perindopril and 6.935 mg amlodipine besilate equivalent to 5 mg amlodipine.
Each tablet contains 10 mg perindopril tosylate equivalent to 6.8 mg perindopril and 13.87 mg amlodipine besilate equivalent to 10 mg amlodipine.
- The other ingredients are sodium hydrogen carbonate (E500), povidone K30, lactose monohydrate, maize starch, microcrystalline cellulose (E460), sodium starch glycolate (type A), magnesium stearate (E572) and calcium hydrogen phosphate (E341).

What [invented name] looks like and contents of the pack

[invented name] 5 mg/5 mg tablets are white, oval, biconvex tablet, debossed "5/5" on one side and plain on the other side.

[invented name] 5 mg/10 mg tablets are white, square-shaped, biconvex tablet, debossed "5/10" on one side and plain on the other side.

[invented name] 10 mg/5 mg tablets are white, round, biconvex tablet, debossed "10/5" on one side and plain on the other side.

[invented name] 10 mg/10 mg tablets are white, round, biconvex tablet, debossed “10/10” on one side and plain on the other side.

[invented name] stored in tablet containers are available in pack sizes of:

5mg/5mg: 10, 30, 50, 60, 90, 90 (3x30), 100 and 120 (2x60) tablets.

5mg/10mg, 10mg/5mg & 10mg/10mg: 30, 50, 60, 90, 90 (3x30), 100 and 120 (2x60) tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

[To be completed nationally]

Manufacturer

TEVA Pharmaceutical Works Private Limited Company

Pallagi út 13

4042 Debrecen

Hungary

Teva Operations Poland Sp. z.o.o

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31-546 Krakow

Poland

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Swensweg 5

2031 GA Haarlem

The Netherlands

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Ostravska 29, c.p. 305

74770 Opava-Komarov

Czech Republic

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

Belgium:	Peramteva tabletten
Bulgaria:	Zaprinel A tablets
Croatia:	Articel-Am tablete
Czech Republic:	Perindopril tosilate/amlodipin Teva tablety
Estonia:	Perindopril/Amlodipine Teva
Ireland:	Perindopril tosilate/Amlodipine Teva Tablets
Italy:	PERINDOPRIL E AMLODIPINA TEVA
Latvia:	Perindopril/Amlodipine Teva tabletes
Netherlands:	Perindopril tosilaat/Amlodipine Teva tabletten
Poland:	Perindopril+Amlodipine Teva Pharmaceuticals
Portugal:	Perindopril + Amlodipina ratiopharm
Slovenia:	Perodilam tablete

This leaflet was last revised in {MM/YYYY}.