

Package leaflet: Information for the user

Perindopril /Indapamide STADA < 2 mg/0.625 mg Tablets

Perindopril /Indapamide STADA 4 mg/1.25 mg Tablets

Perindopril tert-butylamine / Indapamide

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

1. What Perindopril/Indapamide is and what it is used for

What is Perindopril/Indapamide ?

Perindopril/Indapamide is a combination of two active ingredients, perindopril and indapamide. It is an anti-hypertensive and is used in the treatment of high blood pressure (hypertension).

What is Perindopril/Indapamide used for?

Perindopril belongs to a class of medicines called ACE inhibitors. These work by widening the blood vessels, which makes it easier for your heart to pump blood through them. Indapamide is a diuretic. Diuretics increase the amount of urine produced by the kidneys. However, indapamide is different from other diuretics, as it only causes a slight increase in the amount of urine produced. Each of the active ingredients reduces blood pressure and they work together to control your blood pressure.

2. What you need to know before you take Perindopril/Indapamide

DO NOT take Perindopril/Indapamide

- if you are allergic to perindopril or any other ACE inhibitor, or to indapamide or any other sulphonamides or any of the other ingredients of this medicine (listed in section 6)
- 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 severe liver disease or suffer from a condition called hepatic encephalopathy (degenerative disease of the brain)
- if you have a severe kidney disease or if you are receiving dialysis
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren

- if you have low or high blood potassium
- if you are suspected of having untreated decompensated heart failure (severe water retention, difficulty in breathing)
- if you are more than 3 months pregnant (It is also better to avoid Perindopril/Indapamide in early pregnancy - see “Pregnancy and Breast-feeding”)
- if you are breast-feeding
- 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 before taking Perindopril/Indapamide :

- 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 or problems with your kidneys
- if you have liver problems
- if you suffer from a collagen disease (skin disease) such as systemic lupus erythematosus or scleroderma
- if you have atherosclerosis (hardening of the arteries)
- if you suffer from hyperparathyroidism (overactive parathyroid gland)
- if you suffer from gout
- if you are taking any of the following medicines, the risk of angioedema (rapid swelling under the skin in area such as the throat) 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 diabetes
- if you are on a salt restricted diet or use salt substitutes which contain potassium
- if you take lithium or potassium-sparing diuretics (spironolactone, triamterene) as their use with Perindopril/Indapamide should be avoided (see “Other medicines and Perindopril/Indapamide ”)
- if you experience a decrease in vision or eye pain. These could be symptoms of fluid accumulation in the vascular layer of the eye (choroidal effusion) or an increase of pressure in your eye and can happen within hours to weeks of taking Perindopril/Indapamide . This can lead to permanent vision loss, if not treated. If you earlier have had a penicillin or sulfonamide allergy, you can be at higher risk of developing this.
- 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/Indapamide ”

You must tell your doctor if you think that you are (or might become) pregnant. Perindopril/Indapamide 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 and breast-feeding”).

When you are taking Perindopril/Indapamide , you should also inform your doctor or the medical staff:

- if you are to undergo anaesthesia and/or surgery
- if you have recently suffered from diarrhoea or vomiting, or are dehydrated
- if you are to undergo dialysis or 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 are to undergo a medical test that requires injection of an iodinated contrast agent (a substance that makes organs like kidney or stomach visible on an X-ray)

Athletes should be aware that Perindopril/Indapamide contains an active ingredient (indapamide) which may give a positive reaction in drug tests.

Children and adolescents

Perindopril/Indapamide should not be given to children.

Other medicines and Perindopril/Indapamide

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

You should avoid Perindopril/Indapamide with:

- lithium (used to treat depression)
- Potassium supplements (including salt substitutes), potassium-sparing diuretics (spironolactone, triamterene) 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)

Treatment with Perindopril/Indapamide 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 treating high blood pressure
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/Indapamide ” and “Warnings and precautions”)
- procainamide (for the treatment of an irregular heartbeat)
- allopurinol (for the treatment of gout)
- terfenadine or astemizole (antihistamines for hay fever or allergies)
- corticosteroids used to treat various conditions including severe asthma and rheumatoid arthritis
- immunosuppressants used for the treatment of auto-immune disorders or following transplant surgery to prevent rejection (e.g. ciclosporin)
- medicines for the treatment of cancer
- erythromycin by injection (an antibiotic)
- halofantrine (used to treat certain types of malaria)
- pentamidine (used to treat pneumonia)
- injectable gold (used to treat rheumatoid polyarthritis)
- vincamine (used to treat symptomatic cognitive disorders in elderly including memory loss)
- bepridil (used to treat angina pectoris)
- sultopride (for the treatment of psychoses)
- medicines used for heart rhythm problems (e.g. quinidine, hydroquinidine, disopyramide, amiodarone, sotalol)
- digoxin or other cardiac glycosides (for the treatment of heart problems)
- baclofen (to treat muscle stiffness occurring in diseases such as multiple sclerosis)
- medicines to treat diabetes such as insulin or metformin
- calcium including calcium supplements

- stimulant laxatives (e.g. senna)
- non-steroidal anti-inflammatory drugs (e.g. ibuprofen) or high dose salicylates (e.g. acetylsalicylic acid)
- amphotericin B by injection (to treat severe fungal disease)
- medicines to treat mental disorders such as depression, anxiety, schizophrenia (e.g. tricyclic antidepressants, neuroleptics such as amisulpride, sulpiride, tiapride, haloperidol, droperidol)
- tetracosactide (to treat Crohn's disease)
- medicines, which are most often used to treat diarrhoea (racecadotril) or avoid rejection of transplanted organs (sirolimus, everolimus, temsirolimus and other medicines belonging to the class of so-called mTor inhibitors). See section "Warnings and precautions"

- **Perindopril/Indapamide with food and drink**

It is preferable to take Perindopril/Indapamide before a meal.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, as 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/Indapamide before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Perindopril/Indapamide. Perindopril/Indapamide 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

You must not take Perindopril/Indapamide if you are breast-feeding.

Tell your doctor immediately if you are breast-feeding or about to start breast-feeding.

See your doctor immediately.

Driving and using machines

Perindopril/Indapamide usually does not affect alertness but different reactions such as dizziness or weakness in relation to the decrease in blood pressure may occur in certain patients. If affected, your ability to drive or to operate machinery may be impaired.

Perindopril/Indapamide tablets contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Perindopril/Indapamide

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is one tablet once a day. Your doctor may decide to increase the dose to 2 tablets daily or to modify the dosage regimen if you suffer from renal impairment.

Method of administration

Take your tablet preferably in the morning and before a meal. Swallow the tablet with a glass of water.

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is one tablet once a day. Your doctor may decide to modify the dosage regimen if you suffer from renal impairment.

Method of administration

Take your tablet preferably in the morning and before a meal. Swallow the tablet with a glass of water.

If you take more Perindopril/Indapamide than you should

If you take too many tablets, contact your doctor or nearest hospital casualty department immediately. The most likely effect in case of overdose is low blood pressure. If marked low blood pressure occurs (symptoms such as dizziness or faintness), lying down with the legs raised can help.

If you forget to take Perindopril/Indapamide

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/Indapamide, 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/Indapamide

As the treatment for high blood pressure 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 heartbeat

In decreasing order of frequency, side effects can include:

- **Common (may affect up to 1 in 10 people):** headache, feelings of 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, epigastric pain, anorexia, vomiting, abdominal pain, taste disturbances, dry mouth, dyspepsia or difficulty of digestion, diarrhoea, constipation), allergic reactions (such as skin rashes, itching), cramps, feeling of tiredness, low potassium in the blood
- **Uncommon (may affect up to 1 in 100 people):** mood swings, sleep disturbances, bronchospasm (tightening of the chest, wheezing and shortness of breath), angioedema (symptoms such as wheezing, swelling of the face or tongue), urticaria, purpura (red pinpoint spots on skin), kidney problems, impotence (inability to obtain or maintain an erection), sweating, depression, low sodium in the blood that may lead to dehydration and low blood pressure
- **Rare (may affect up to 1 in 1,000 people):** psoriasis worsening, flushing, decreased or absent urine output, acute renal failure; 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). Low chloride in the blood, low magnesium in the blood
- **Very rare (may affect up to 1 in 10,000 people):** confusion, cardiovascular disorders (irregular heartbeat, angina, heart attack), eosinophilic pneumonia (a rare type of

pneumonia), rhinitis (blocked up or runny nose), severe skin manifestations such as erythema multiforme. If you suffer from systemic lupus erythematosus (a type of collagen disease), this might get worse. Cases of photosensitivity reactions (change in skin appearance) after exposure to the sun or artificial UVA have also been reported

- **Not known (frequency cannot be estimated from the available data):** fainting, life-threatening irregular beat (Torsade de pointes), abnormal ECG heart tracing, increased levels of liver enzymes, discoloration, numbness and pain in fingers or toes (Raynaud's phenomenon), decrease in vision or pain in your eyes due to high pressure (possible signs of fluid accumulation in the vascular layer of the eye (choroidal effusion) or acute angle-closure glaucoma)

Disorders of the blood, kidney, liver or pancreas and changes in laboratory parameters (blood tests) can occur. Your doctor may need to give you blood tests to monitor your condition. In cases of hepatic insufficiency (liver problems), there is a possibility of onset of hepatic encephalopathy (degenerative disease in the brain).

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 Perindopril/Indapamide

This medicinal product has to be stored in the original package. 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 the blister. The expiry date refers to the last day of the month.

Once opening the pouch the tablets should be used within 2 months.

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/Indapamide contains

- The active substances are Perindopril tert-butylamine and Indapamide
- Each tablet contains 2 mg of perindopril tert-butylamine and 0.625 mg indapamide
- Each tablet contains 4 mg of perindopril tert-butylamine and 1.25 mg indapamide

The other ingredients are:

- Lactose Monohydrate
- Magnesium stearate
- Silica, hydrophobic colloidal anhydrous
- Microcrystalline cellulose

What Perindopril/Indapamide looks like and contents of the pack

Perindopril/Indapamide White, rod shaped tablets engraved with 'P' and 'I' on either side of the score line on one side and a score line on the other side. The tablets are packed in PVC /

PVdC – Aluminium blisters within a protective aluminium wrapper, including a desiccant protecting the tablets from moisture. The desiccant should not be swallowed.

Perindopril/Indapamide White, rod shaped tablets having 'PI' debossed on one side and plain on the other side. The tablets are packed in PVC / PVdC – Aluminium blisters within a protective aluminium wrapper, including a desiccant protecting the tablets from moisture. The desiccant should not be swallowed.

Pack Sizes

20, 30, 50, 60, 90, 100, 120, 150 and 180.

*Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

STADA Arzneimittel AG
Stadastrasse 2-18
61118 Bad Vilbel
Duitsland

Fabrikant

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Fibichova 143
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Tsjechië

STADA Arzneimittel AG
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Duitsland

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Via della Pace, 25A
41030 San Prospero (MO) Italië

In het register ingeschreven onder

Perindopril tert-butylamine/Indapamide STADA 2/0,625 mg, tabletten RVG 107487

Perindopril tert-butylamine/Indapamide STADA 4/1,25 mg, tabletten RVG 107490

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

NL: Perindopril tert-butylamine/Indapamide STADA 2/0,625 mg tabletten and Perindopril tert-butylamine/Indapamide STADA 4/1,25 mg tabletten

HU: Perindopril/Indapamid Stada 2 mg/0,625 mg tableta and Perindopril/Indapamid Stada 4 mg/1,25 mg tableta

PT: Perindopril + Indapamide Ciclum, 2 mg + 0.625 mg Comprimido and Perindopril + Indapamide Ciclum 4 mg + 1.25 mg, Comprimido

Deze bijsluiter is voor het laatst goedgekeurd in mei 2022.