

Package leaflet: Information for the user

Perindopril/Indapamide 2 mg/0.625 mg Tablets

Perindopril/Indapamide 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.

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

Perindopril/Indapamide is a combination of Perindopril and Indapamide. They belong to a group of anti-hypertensive medicines, which are used in the treatment of high blood pressure.

Perindopril belongs to a class of ACE inhibitors. These work by widening the blood vessels in your body, which make it easier for your heart to pump blood around through them.

Indapamide belongs to a group of medicines called diuretics. These work by allowing your kidneys to produce more urine than normal.

Each of the individual medicines work together to lower your blood pressure and control it.

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

DO NOT take Perindopril/Indapamide

- if you are allergic to perindopril or indapamide or any of the other ingredients of this medicine (listed in section 6)
- if you are allergic to any other ACE inhibitors or diuretics (Sulphonamides)
- if you have experienced swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing, with previous ACE inhibitor therapy. This is a condition called angioneurotic oedema (Quincke's oedema)
- alternatively, if you or any of your family members have had these symptoms tell your doctor as soon as possible
- if you have heart problems or are on medication (see "Other medicines and Perindopril/Indapamide")
- if you are more than 3 months pregnant. (It is also better to avoid Perindopril/Indapamide in early pregnancy – see pregnancy section.)
- if you are breast-feeding (see breast-feeding section)
- if you have kidney failure or 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 serious liver disease or suffer from a condition called hepatic encephalopathy (which is brain and nervous system impairment caused by severe liver disease)
- if your doctor has told you, that you have low or high blood potassium
- 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 this medicine:

- if you have bilateral renal artery stenosis (narrowing of the main blood vessel leading to the kidney) or a single functioning kidney
- if you have diabetes
- if you are on a low salt diet or use salt substitutes, which contain potassium
- if you take lithium or potassium-sparing diuretics (e.g. spironolactone, triamterene)
- if you are taking a medicine which is a combination with a potassium-sparing diuretic
- if you are going to have an operation under general anaesthetic, as you may need to stop treatment a few days beforehand
- if you have atherosclerosis (a disease of the arteries in which blood vessel walls thicken and harden due to cholesterol deposit)
- 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 (e.g. bee or wasp sting)
- if you are to undergo a medical test that requires injection of a substance that makes organs like the kidney or stomach visible on an x-ray (iodinated contrast agent)
- if you have anaemia (a condition when the red blood cells in your body carry less oxygen, some of the symptoms of anaemia include tiredness, headaches, dizziness)
- if you have gout (a disease where uric acid crystals cause swollen joints)
- if you have a collagen disease such as systemic lupus erythematosus or scleroderma
- you must tell your doctor if you think 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 section)
- 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 (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 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.

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”.

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
- Potassium supplements (including salt substitutes), potassium-sparing diuretics (e.g. spironolactone, triamterene alone or in combination) 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)
- allopurinol (treatment of gout)
- procainamide (treatment of irregular heartbeat)
- systemic corticosteroids (used to treat various conditions including severe asthma and rheumatoid arthritis)
- other medicines to treat 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”).

- immunosuppressants used for the treatment of auto-immune disorders or following transplant surgery to prevent rejection (e.g. ciclosporin)

Treatment with Perindopril/Indapamide can be affected by other medicines. Tell your doctor if you are taking any of the following medicines as special care may be required:

- astemizole or terfenadine (antihistamines for hayfever or allergies)
- bepridil (used to treat angina pectoris - an uncomfortable feeling in this chest)
- erythromycin by injection, moxifloxacin, sparfloxacin (antibiotics)
- halofantrine (used to treat certain types of malaria)
- pentamidine (used to treat pneumonia which is a serious lung infection)
- vincamine (used to treat disorders of the brain in elderly)
- baclofen (to treat muscle stiffness occurring in diseases such as multiple sclerosis)
- medicines to treat diabetes such as insulin, metformin or hypoglycaemic sulphonamides
- Non-Steroidal anti-inflammatory drugs (e.g. ibuprofen) or high dose salicylates (e.g. acetylsalicylic acid)
- potassium lowering drugs e.g. amphotericin B (by injection. to treat severe fungal disease), glucocorticoids and mineralocorticoids (systemic route), or stimulant laxatives (e.g. senna)
- potassium-sparing diuretics (amiloride, spironolactone, triamterene)
- thiazide or loop diuretics
- medicines to treat irregular heart beat such as quinidine, hydroquinidine, disopyramide, amiodarone, bretylium, dofetilide, ibutilide and sotalol
- medicines to treat mental disorders such as depression, anxiety, schizophrenia (e.g. tricyclic antidepressants, neuroleptics such as chlorpromazine, cyamemazine
- levomepromazine, thioridazine, trifluoperazine, amisulpiride, tiapride, droperidol, haloperidol, pimozide)
- cisapride, diphemanil, mizolastine
- methadone
- sultopride (used in the treatment of psychotic disorders)
- tetracosactide (used to treat Crohn’s disease)
- calcium salts
- 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 recommended that Perindopril/Indapamide are taken in the morning on an empty stomach. Swallow the tablets with a glass of water.

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 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

Tell your doctor if you are breast-feeding or about to start breast-feeding. Perindopril/Indapamide must not be taken by 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 (see section "Do not take Perindopril/Indapamide"). See your doctor immediately.

Driving and using machines

Perindopril/Indapamide has minor or moderate influence on the ability to drive and use machines. This medicine does not affect alertness but reactions related to low blood pressure may occur in some patients. This can cause dizziness or weakness. If affected your ability to drive or operate machinery may be impaired therefore caution is advised.

Perindopril/Indapamide 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 dose may be increased depending on your condition and other medicines you are taking. Take Perindopril/Indapamide your medicine by mouth only.

The recommended dose is:

High Blood pressure:

It is recommended that one Perindopril/Indapamide 2 mg/0.625 mg tablet is taken in the morning before breakfast. If your blood pressure is not controlled then your doctor may increase your dose to one Perindopril/Indapamide 4 mg/1.25 mg tablet daily.

In older people with high blood pressure:

It is recommended that one Perindopril/Indapamide 2 mg/0.625 mg tablet is taken in the morning before breakfast.

If you take more Perindopril/Indapamide than you should

If you take more Perindopril/Indapamide than you should or someone else has taken your medicine contact your doctor or pharmacist immediately. The most common effect of an overdose is low blood pressure, the symptoms of this can be dizziness, sleepiness or nausea. It may help lying down with your legs raised up into the air.

If you forget to take Perindopril/Indapamide

Take your tablet as soon as you remember unless it is time for your next dose. Take your next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

If you stop taking Perindpril/Indapamide

If you stop taking Perindopril/Indapamidetell your doctor as soon as possible. Normally the treatment for high blood pressure is long term.

If you have any further questions on the use of this medicines, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. These can include:

Common (may affect up to 1 in 10 people)

- dry cough
- dry mouth
- constipation
- nausea (feeling sick)
- stomach pain or discomfort
- loss of appetite
- taste loss
- low potassium in the blood

Uncommon (may affect up to 1 in 100 people)

- low blood pressure
- headache
- feeling light headed when standing up
- feelings of dizziness
- mood swings
- sleep disturbance
- hypersensitivity reaction (allergic reaction)
- cramps
- paraesthesia (numbness or pins and needles on your hands or feet)
- depression
- low sodium in the blood that may lead to dehydration and low blood pressure
- impotence (inability to obtain or maintain an erection)

Rare (may affect up to 1 in 1,000 people)

- raised levels of calcium in the blood
- psoriasis worsening
- acute renal failure
- decreased or absent urine output
- 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)
- flushing
- low chloride in the blood
- low magnesium in the blood

Very rare (may affect up to 1 in 10,000 people)

- thrombocytopenia: low blood platelet count. Symptoms may include bleeding or bruising more easily than normal
- leukopenia or agranulocytosis: lack of white blood cells. Symptoms may include frequent infections such as fever, severe chills, sore throat or mouth ulcers

- aplastic anaemia: a rare type of anaemia in which there is a reduction in your red blood cells, white blood cells and platelets
- haemolytic anaemia: illness resulting from the destruction of red blood cells
- anaemia in patients following a kidney transplant or on haemodialysis
- pancreatitis: inflammation of the pancreas in case of hepatic failure
- hepatic encephalopathy: brain and nervous system damage related to complicated liver disease

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

- discolouration, numbness and pain in fingers and 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)

If you have any blood tests, tell the doctor that you are taking <Product name> since the following may be seen:

- high levels of potassium
- high levels of uric acid and glucose
- slightly high levels of urea and creatinine

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 {to be completed nationally: 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

Keep this medicine out of the sight and reach of children.

For 2mg and 4mg: PVC / PVdC – Aluminium blisters:

Store in the original package to protect from moisture.

When unopened, this medicinal product does not require any special temperature storage conditions.

Once the laminated pouch is opened, blister strips should be stored in the outer box below 30° C. Any remaining tablets should be discarded two months after opening the pouch.

For 4mg: Aluminium-Aluminium blisters:

Store in the original package to protect from moisture. Store below 30°C.

Do not use this medicine after the expiry date which is stated on the label. The expiry date refers to the last day of the month.

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 Perindopril tert-butylamine equivalent to 1.669 mg perindopril and 0.625 mg Indapamide
- Each tablet contains 4 mg Perindopril tert-butylamine equivalent to 3.338 mg perindopril and 1.25 mg Indapamide

- *The other ingredients are:*

Lactose Monohydrate

Magnesium stearate

Silica, hydrophobic colloidal

Cellulose, Microcrystalline

What Perindopril/Indapamide looks like and contents of the pack

Perindopril/Indapamide 2 mg/0.625 mg Tablet

White, rod shaped tablets engraved with 'P' and 'I' on either side of the break-line on one side and a break-line on the other side. The tablet can be broken into equal doses.

Perindopril/Indapamide 4 mg/1.25 mg Tablet

White rod shaped tablets having 'PI' debossed on one side and plain on the other.

For 2mg and 4mg: PVC / PVdC – Aluminium blisters:

The tablets are packed in PVC / PVdC – Aluminium blisters within a protective aluminium pouch, including a desiccant protecting the tablets from moisture. The desiccant should not be swallowed.

For 4mg: Aluminium-Aluminium blisters:

The tablets are packed in Aluminium-Aluminium blisters packed in a carton.

Pack Sizes

30, 90 and 100

*Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

STADA Arzneimittel AG

Stadastrasse 2-18

61118 Bad Vilbel

Duitsland

In het register ingeschreven onder

Perindopril/Indapamide STADA 2/0,625 mg, tabletten RVG 106101

Perindopril/Indapamide STADA 4/1,25 mg, tabletten RVG 106100

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

BG: Pontea

NL: Perindopril/Indapamide STADA 2/0,625 mg/4/1,25 mg, tabletten

SK: Perindostad Kombi 2 mg/0,625 mg/4 mg/1,25 mg Tablety

ES: Perindopril/Indapamida STADA 2/0.625 mg/4/1.25 mg comprimidos EFG

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