

Perindopril APOTEX

Perindopril erbumine

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

This leaflet answers some common questions about perindopril. It does not contain all the available information about this medicine. It does not take the place of talking to your doctor or pharmacist. If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking this medicine against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may want to read it again.

What this medicine is used for

Perindopril is used to treat high blood pressure (also known as hypertension), heart failure or coronary artery disease.

Perindopril belongs to a group of medicines called angiotensin converting enzyme (ACE) inhibitors.

High blood pressure

Perindopril helps to lower your blood pressure. Everyone has blood pressure, which helps to circulate blood all around the body. Your

blood pressure may be different at different times of the day, depending on how busy or worried you are. You have high blood pressure when your blood pressure stays higher than is needed, even when you are relaxed. There are usually no symptoms of high blood pressure. The only way of knowing that you have it is to have your blood pressure checked on a regular basis. Untreated high blood pressure can lead to serious health problems, such as stroke, heart disease and kidney failure.

Heart failure

Perindopril helps to treat heart failure. Heart failure means that the heart muscle is not pumping blood strongly enough to circulate blood around the body properly. Heart failure is not the same as a heart attack and does not mean that the heart stops working. Heart failure may start off with no symptoms, but as the condition progresses, you may feel short of breath or get tired easily after light physical activity such as walking. Fluid may accumulate in the body, such as swollen ankles and feet. In severe heart failure, symptoms like breathlessness may occur even at rest. If you follow your doctor's advice, your ability to perform daily activities may improve. You may breathe more easily, feel less tired and have less swelling.

Coronary artery disease

Coronary artery disease is the narrowing of the vessels carrying blood to the heart. Perindopril has

been shown to reduce some risks of coronary artery disease, including heart attacks.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed this medicine for another reason.

This medicine is available only with a doctor's prescription.

This medicine is not addictive.

There is not enough information to recommend the use of this medicine for children. This medicine should not be used in children.

Before you take this medicine

When you must not take it

Do not take this medicine if you have an allergy to:

- perindopril
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin.

Do not take this medicine if you have or have had any of the following medical conditions:

- diabetes or kidney impairment and are taking aliskiren to treat high blood pressure
- undergoing renal dialysis or haemofiltration using polyacrylonitrile membranes
- unilateral or bilateral renal artery stenosis (narrowing of the blood vessels to one or both kidneys that reduces the blood supply to your kidneys).
- You have experienced symptoms such as wheezing, swelling of the face, tongue, lips 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 either spontaneously or, in response to another medicine in the past (a rare condition called angioedema).
- you undergo treatments where your blood is treated outside of the body (also known as extracorporeal treatments) that may increase your risk of allergic reactions, treatments such as: - renal dialysis or haemofiltration using polyacrylonitrile membranes. - low-density lipoprotein (LDL) apheresis, a technique where LDL is 'filtered' out of the blood, using dextran sulphate.
- intolerance or allergy to lactose (this medicine contains lactose).

Do not take this medicine if you are taking a combined medicine called sacubitril/valsartan, used to treat long-term heart failure.

Do not take this medicine if you are pregnant or plan to become pregnant.

Perindopril may affect your developing baby if you take it during pregnancy.

Do not take this medicine if you are breastfeeding.

It is not known if perindopril passes into human breast milk.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- aortic stenosis (narrowing of the main blood vessel leading from the heart)
- kidney disease or if you are on renal dialysis
- liver disease
- heart disease, including hypertrophic cardiomyopathy (heart muscle disease)
- low blood pressure
- diabetes
- aortic stenosis (narrowing of the main blood vessel leading from the heart)
- high or low levels of potassium, sodium or other problems with salt balance
- systemic lupus erythematosus or scleroderma (a disease affecting the skin, joints and kidneys)
- have abnormally increased levels of a hormone called aldosterone in your blood (primary aldosteronism).

Tell your doctor straight away if:

- you are on a salt restricted diet or use salt substitutes containing potassium
- you are undergoing, or you are intending to undergo, treatments where your blood is treated outside of the body (also known as extracorporeal treatments)

- you are undergoing, or have had an allergic reaction during, previous low-density lipoprotein (LDL) apheresis, a technique where LDL is 'filtered' out of a patient's blood, using dextran sulphate
- you have recently suffered from diarrhoea or vomiting or are dehydrated.
- you have an intolerance to some sugars as this medicine contains lactose
- you are taking lithium (used to treat mania or depression).
- you are undergoing desensitisation treatment or have had an allergic reaction during previous desensitisation treatment (e.g. treatments using bee, wasp or ant venom).
- you are pregnant or become pregnant while taking this medicine, as it may cause serious harm to your baby.

Tell your doctor if you also take an angiotensin II receptor blocker (e.g. valsartan, telmisartan, irbesartan), in particular if you have diabetes-related kidney problems.

Tell your doctor if you are taking aliskiren.

Tell your doctor you are of African origin since you may have a higher risk of angioedema and this medicine is less effective in lowering your blood pressure.

Tell your doctor if you are planning to have surgery, dental treatment or an anaesthetic.

If you have not told your doctor about any of the above, tell them before you start taking this medicine. If you think any of these situations apply to you, or you have any doubts or questions about taking this medication consult your doctor or pharmacist.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any

that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interact with perindopril. These include:

- some antibiotics and medicines used to treat infection
- some anti-inflammatory drugs for pain relief (e.g. high dose aspirin, ibuprofen)
- medicines used to treat mood disorders and some types of depression (e.g. lithium, tricyclic antidepressants, antipsychotics)
- potassium-sparing diuretics, sources of potassium, like potassium tablets, salt substitutes containing potassium, other drugs which can increase potassium in your body (such as heparin and co-trimoxazole also known as trimethoprim/sulfamethoxazole)
- some treatments where your blood is treated outside of the body, also known as extracorporeal treatments
- heparin, used to thin the blood
- immunosuppressants, medicines which reduce the activity of the body's natural defences
- some medications used to treat high blood pressure (including angiotensin receptor blockers), aliskiren, diuretics (sometimes called "fluid" or "water" tablets because they increase the amount of urine passed each day)
- medications used to treat fast or irregular heartbeat and other heart conditions vasodilators (e.g. nitrates)
- medicines used to treat diabetes (tablets and insulin)
- medicines which may affect the blood cells, such as allopurinol, procainamide
- baclofen (a medicine used to treat muscle stiffness in diseases such as multiple sclerosis)
- Medicines used for the treatment of low blood pressure, shock or asthma (e.g. ephedrine,

noradrenaline or adrenaline (epinephrine))

- Gold salts, especially with intravenous administration (used to treat symptoms of rheumatoid arthritis)
- medicines which may increase the risk of angioedema (a severe allergic reaction) such as: - mammalian target of rapamycin (mTOR) inhibitors used to avoid rejection of transplanted organs (e.g. temsirolimus, sirolimus, everolimus) - sacubitril (available as fixed - dose combination with valsartan), used to treat long-term heart failure.

These medicines may be affected by this medicine or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine. It is a good idea to remind your doctor of all other medicines you take.

Other medicines not listed above may also interact with perindopril.

How to take this medicine

Follow all directions given to you by your doctor carefully.

They may differ to the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

Your doctor will tell you how much of this medicine you should take.

This will depend on your condition, such as elderly people or severe kidney failure, and whether you are taking any other medicines.

High blood pressure, coronary artery disease

The dose you may need each day will be decided and adjusted by your doctor. This will normally be 2 mg, 4mg or 8mg once daily.

Heart failure

The dose you may need each day will be decided and adjusted by your doctor. This will normally be 2 mg to 4mg once daily.

How to take it

Swallow your tablet whole with a glass of water.

When to take it

Take it at about the same time each day, preferably in the morning before a meal.

Taking your medicine at the same time each day will have the best effect. It will also help you remember when to take it.

How long to take it for

Continue taking your medicine for as long as your doctor tells you.

Perindopril can help control your condition, but cannot cure it. It is important to keep taking your medicine even if you feel well.

Make sure you have enough to last over weekends and holidays.

If you forget to take it

If it is almost time to take your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for missed doses.

This may increase the chance of you experiencing side effects.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much perindopril, your blood pressure may fall (also known as hypotension), which can make you feel dizzy or faint. If this happens, lying down with the legs elevated can help. Other effects like sickness, cramps, sleepiness, confusion, kidney problems, salt and water disturbances are possible.

While you are taking this medicine

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking this medicine.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

If you become pregnant while taking this medicine, tell your doctor immediately.

Tell your doctor if you are about to have any blood tests.

Tell your doctor if you are going to have surgery or an anaesthetic or are going into hospital.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects.

Make sure you drink enough water during exercise and hot weather especially if you sweat a lot. This

will help you avoid any dizziness or light-headedness caused by a sudden drop in blood pressure.

Tell your doctor straight away if you have excessive vomiting or diarrhoea while taking this medicine.

Things you must not do

Do not give this medicine to anyone else, even if they have the same condition as you.

Do not take your medicine to treat any other complaint unless your doctor tells you to.

Do not stop taking your medicine or change the dosage without first checking with your doctor.

Do not stop taking your tablets because you are feeling better, unless advised by your doctor.

Things to be careful of

Be careful while driving or operating machinery until you know how perindopril affects you.

Dizziness or weakness due to low blood pressure may occur in certain patients. If you have any of these symptoms do not drive or operate machinery or do anything else that could be dangerous.

Side effects

Tell your doctor and pharmacist as soon as possible if you do not feel well while you are taking perindopril.

This medicine helps most people, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Angioedema (a severe allergic reaction) has been reported in patients treated with ACE inhibitors. This may occur at any time during treatment. If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to Accident and Emergency at your nearest hospital. These side effects are extremely rare but can become serious:

- swelling of your extremities (limbs, hands or feet), lips, face, mouth, tongue or throat
- difficulty breathing, shortness of breath, wheezing
- purple spots with occasional blisters on the front of your arms, legs, around your neck and ears (Stevens-Johnson Syndrome)
- severe blisters, skin rash, itching, erythema multiforme or other allergic reactions
- changes in the rhythm or rate of the heartbeat
- fast or irregular heartbeat
- fever, chest pain, shortness of breath, feeling unwell (signs of eosinophilic pneumonia)
- feeling of tightness, pressure or heaviness in the chest (signs of myocardial infarction, angina)
- frequent infections, fever, severe chills, sore throat or mouth ulcers (may be caused by a lack of white blood cells)
- stroke.

These are very serious side effects and you may need urgent medical attention or hospitalisation.

Talk to your doctor or pharmacist if you notice any of the following side effects:

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

- Cough, often described as dry and irritating, shortness of breath, discomfort on exertion
- Headache, dizziness, vertigo, pins and needles

- Changes in the rhythm or rate of the heart beat, fast or irregular heart beat
- Feeling tired, lethargic or weak
- Tinnitus (persistent noise in the ears), vision disturbances
- Hypotension, flushing, impaired peripheral circulation, vasculitis, nose bleeds
- Nausea, vomiting, taste disturbances, indigestion, diarrhoea, constipation, stomach pain or discomfort
- Muscle cramps
- Rash, pruritus (itching).

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

- High levels in the blood of potassium, urea and/or creatine, low sodium levels in the blood
 - Mood disturbance, sleep disturbances (difficulty sleeping, abnormal dreams), feeling sleepy or drowsy, fainting
 - Difficulty breathing or wheezing
 - Dry mouth
 - Swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing
 - Excessive sweating
- Increased sensitivity of the skin to sun, skin rash or inflammation of the skin often including blisters that weep and become crusted
- Increase in some white blood cells
 - Erectile dysfunction
 - Fever or high temperature
 - Chest pain
 - Kidney problems
 - Decreased blood sugar levels
 - Aching muscles, muscle tenderness or weakness, not caused by exercise
 - Generally feeling unwell
 - Falls.

Rare (may affect up to 1 in 1,000 people) side effects can include:

- Elevation of bilirubin levels in the blood, increases in liver enzymes
- Worsening of psoriasis.

Very rare (may affect up to 1 in 10,000 people) side effects can include:

- Hepatitis
- Inflammation of the pancreas (pancreatitis)
- Kidney disease
- Eosinophilic pneumonia
- Runny or blocked nose, sneezing, facial pressure or pain
- Red, often itchy spots, similar to the rash of measles, which starts on the limbs and sometimes on the face and the rest of the body.
- Joint pain
- Swelling of hands, ankles or feet
- Bleeding or bruising more easily than normal caused by a low blood platelet count, frequent infections such as fever, severe chills, sore throat or mouth ulcers caused by a lack of white blood cells, pancytopenia (a rare type of anaemia)
- Illnesses resulting from a lack of red blood cells
- Stroke, myocardial infarction, angina pectoris (a feeling of tightness, pressure or heaviness in the chest)
- Changes in the rhythm or rate of the heart beat
- Confusion, depression or hallucinations.

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

- Discolouration, numbness and pain in fingers or toes (Raynaud's phenomenon).

Other:

Concentrated urine (dark in colour), feel or are sick, have muscle cramps, confusion and fits which may be due to inappropriate anti-diuretic hormone (ADH) secretion can occur with ACE inhibitors. If you have

these symptoms contact your doctor as soon as possible.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may occur in some patients and you should ask your doctor, pharmacist or nurse if you want to know more.

Storage and disposal

Storage

Keep your medicine in the pack until it is time to take it.

If you take your medicine out of the pack it may not keep well.

Keep your medicine in a cool, dry place where the temperature stays below 25°C. Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep this medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine left over.

Product Description

What it looks like

2 mg tablets: light pink to pink-coloured capsule-shaped tablets debossed with 'P' and '9' on either side of the score line on one side and deep break-line on other side.

Blister packs of 30 tablets. AUST R 304690.

4 mg tablets: white to off-white capsule-shaped tablets debossed with 'P' and '9' on either side of the score

line on one side and deep break-line on other side.

Blister packs of 30 tablets. AUST R 304691.

8 mg tablets: white to off-white capsule-shaped tablets debossed with 'P' and '6' on either side of the break-line on one side and break-line on other side.

Blister packs of 30 tablets. AUST R 304692.

* Not all strengths may be available.

Ingredients

Each tablet contains 2 mg, 4 mg or 8 mg perindopril erbumine as the active ingredient.

It also contains the following:

- lactose monohydrate
- magnesium stearate
- microcrystalline cellulose
- colloidal anhydrous silica

Additionally, the 2mg tablet contains iron oxide red as colourant.

This medicine does not contain gluten, sucrose, tartrazine or any other azo dyes.

Sponsor

Apotex Pty Ltd
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