

Package leaflet: Information for the patient

Perindopril tert-butylamine 8 mg tablets

perindopril tert-butylamine

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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Perindopril tert-butylamine 8 mg tablets is and what it is used for
2. What you need to know before you take Perindopril tert-butylamine 8 mg tablets
3. How to take Perindopril tert-butylamine 8 mg tablets
4. Possible side effects
5. How to store Perindopril tert-butylamine 8 mg tablets
6. Contents of the pack and other information

1. What Perindopril tert-butylamine 8 mg tablets is and what it is used for

Perindopril tert-butylamine 8 mg tablets is an angiotensin converting enzyme (ACE) inhibitor. These work by widening the blood vessels, which makes it easier for your heart to pump blood through them.

Perindopril tert-butylamine 8 mg tablets is used:

- to treat high blood pressure (hypertension)
- to reduce the risk of cardiac events, such as heart attack, in patients with stable coronary artery disease (a condition where the blood supply to the heart is reduced or blocked) and who have already had a heart attack and/or an operation to improve the blood supply to the heart by widening the vessels that supply it.

2. What you need to know before you take Perindopril tert-butylamine 8 mg tablets

Do not take Perindopril tert-butylamine 8 mg tablets:

- if you are allergic to perindopril or any of the other ingredients of this medicine (listed in section 6)
- if you are allergic to other ACE inhibitors
- if you are more than 3 months pregnant. (It is also better to avoid Perindopril tert-butylamine 8 mg tablets in early pregnancy – see pregnancy section)
- if you have experienced symptoms such as wheezing, swelling of the face, tongue 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 in any other circumstances (a condition called ‘angioedema’)
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Perindopril tert-butylamine 8 mg tablets

- 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
- if you have liver problems
- if you have kidney problems or if you are receiving dialysis
- if you suffer from a collagen vascular disease such as systemic lupus erythematosus or scleroderma
- if you are on a salt restricted diet or use salt substitutes which contain potassium
- if you suffer from diabetes which is not well controlled
- if you are to undergo anaesthesia and/or surgery
- if you have suffered from recent diarrhoea or vomiting, or are dehydrated
- 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 LDL apheresis (which is removal of cholesterol from your blood by a machine)
- if you are of black origin since you may have a higher risk of angioedema and this medicine may be less effective in lowering your blood pressure than in non-black patients
- if you are taking any of the following medicines, the risk of angioedema is increased:
 - racecadotril (used to treat diarrhea)
 - sirolimus, everolimus, temsirolimus and other drugs belonging to the class of so-called mTor inhibitors (used to avoid rejection of transplanted organs)
- 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 tert-butylamine 8 mg tablets”

Angioedema

Angioedema (a severe allergic reaction with swelling of the face, lips, tongue or throat with difficulty in swallowing or breathing) has been reported in patients treated with ACE inhibitors, including perindopril. This may occur at any time during treatment. If you develop such symptoms, you should stop taking /.../ and see a doctor immediately. See also section 4.

You must tell your doctor if you think you are (or might become) pregnant. Perindopril tert-butylamine 8 mg tablets 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).

Children and adolescents

The use of perindopril in children and adolescents up to the age of 18 years is not recommended.

Other medicines and Perindopril tert-butylamine 8 mg tablets

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

Treatment with Perindopril tert-butylamine 8 mg tablets can be affected by other medicines. These include:

- other medicines for high blood pressure including diuretics (water tablets, medicines which increase the amount of urine produced by the kidneys)
- potassium sparing drugs(e.g. triamterene or amiloride); potassium supplements and potassium-containing salt substitutes
- potassium-sparing drugs used in the treatment of heart failure: eplerenone and spironolactone at doses between 12,5 mg to 50 mg by day
- medicines for the treatment of diabetes (such as insulin or metformin) to lower blood sugar
- baclofen (used to treat muscle stiffness in diseases such as multiple sclerosis)
- lithium for mania or depression

- medicines for the treatment of mental disorders such as depression, anxiety, schizophrenia or other psychoses (e.g. tricyclic antidepressants, antipsychotics)
- medicines, which is 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”
- allopurinol used for the treatment of gout
- immunosuppressants (medicines which reduce the defence mechanism of the body) used for the treatment of auto-immune disorders (eg rheumatoid arthritis) or following transplant surgery (e.g. ciclosporin, tacrolimus)
- trimethoprim (for the treatment of infections)
- estramustine (used in cancer therapy)
- procainamide, a treatment for irregular heartbeat
- non-steroidal anti-inflammatory drugs (NSAIDs, e.g. ibuprofen) for pain relief, including aspirin;
- medicines used for the treatment of low blood pressure, shock or asthma (e.g. ephedrine, noradrenaline or adrenaline)
- vasodilators including nitrates (products that make the blood vessels become wider);
- heparin (used to thin the blood)
- gold salts, especially with intravenous administration (used to treat symptoms of rheumatoid arthritis)

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 tert-butylamine 8 mg tablets” and “Warnings and precautions”)

Perindopril tert-butylamine 8 mg tablets with food and drink

It is preferable to take Perindopril tert-butylamine 8 mg tablets 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 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 tert-butylamine 8 mg tablets before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Perindopril tert-butylamine 8 mg tablets. Perindopril tert-butylamine 8 mg tablets 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

Tell your doctor if you are breast-feeding or about to start breast-feeding. Perindopril tert-butylamine 8 mg tablets 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

Perindopril tert-butylamine 8 mg tablets usually does not affect alertness but dizziness or weakness due to low blood pressure may occur in certain patients. If you are affected in this way, your ability to drive or to operate machinery may be impaired.

Perindopril tert-butylamine 8 mg 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 medicinal product.

3. How to take Perindopril tert-butylamine 8 mg tablets

Always take this medicine exactly as your doctor or pharmacist 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.

The recommended dosages are as follows:

High blood pressure: the usual starting and maintenance dose for treatment in adults is 4 mg once a day. After one month, this can be increased to 8 mg a day which is the maximum recommended dose for high blood pressure.

If you are 65 or older, the usual starting dose is 2 mg once a day. After a month, this can be increased to 4 mg once a day and then if necessary to 8 mg once daily.

Stable coronary artery disease: the usual starting dose is 4 mg once daily. After two weeks, this can be increased to 8 mg once daily, which is the maximum recommended dose in this indication.

If you are 65 or older, the usual starting dose is 2 mg once a day. After a week, this can be increased to 4 mg once a day and after a further week to 8 mg once daily.

Use in children and adolescents

Use in children and adolescents is not recommended.

If you take more Perindopril tert-butylamine 8 mg tablets than you should

If you have taken too many tablets, contact your nearest hospital 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 the legs raised can help.

If you forget to take Perindopril tert-butylamine 8 mg tablets

It is important to take your medicine every day as regular treatment works better. However, if you forget to take a dose of Perindopril tert-butylamine 8 mg tablets 8mg, 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 tert-butylamine 8 mg tablets

As the treatment with Perindopril tert-butylamine 8 mg tablets 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 product, ask your doctor or pharmacist.

4. Possible side effects

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

Stop taking the medicinal product and see a doctor immediately if you experience any of the following serious side effects:

- swelling of the face, lips, mouth, tongue or throat, difficulty in breathing (angioedema) (see section 2 “Warning and precaution”) (uncommon – may affect up to 1 in 100 people),
- severe dizziness or fainting due to low blood pressure (common – may affect up to 1 in 10 people),
- unusual fast or irregular heart beat, chest pain (angina) or heart attack (very rare – may affect up to 1 in 10,000 people),
- weakness of arms or legs, or problems speaking which could be a sign of a possible stroke (very rare – may affect up to 1 in 10,000 people),
- sudden wheeziness, chest pain, shortness of breath, or difficulty in breathing (bronchospasm) (uncommon – may affect up to 1 in 100 people),

- inflamed pancreas which may cause severe abdominal and back pain accompanied with feeling very unwell (very rare – may affect up to 1 in 10,000 people),
- yellowing of the skin or eyes (jaundice) which could be a sign of hepatitis (very rare – may affect up to 1 in 10,000 people),
- skin rash which often starts with red itchy patches on your face, arms or legs (erythema multiforme) (very rare – may affect up to 1 in 10,000 people).

Tell your doctor if you notice any of the following side effects:

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

Headache, dizziness, vertigo, pins and needles, vision disturbances, tinnitus (sensation of noises in the ears), cough, shortness of breath (dyspnoea), gastro- intestinal disorders (nausea, vomiting, abdominal pain, taste disturbances, dyspepsia or difficulty of digestion, diarrhoea, constipation), allergic reactions (such as skin rashes, itching), muscle cramps, feeling of weakness

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

Mood swings, sleep disturbances, dry mouth, intense itching or severe skin rashes), formation of blister clusters over the skin, kidney problems, impotence, sweating an excess of eosinophils (a type of white blood cells), somnolence, fainting, palpitations, tachycardia, vasculitis (inflammation of blood vessels), photosensitivity reaction (increased sensitivity of the skin to sun), arthralgia (joint pain), myalgia (muscle pain), chest pain, malaise, oedema peripheral, fever, fall, 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 (may affect up to 1 in 1,000 people):

Changes in laboratory parameters: Increased level of liver enzymes, high level of serum bilirubin, psoriasis worsening.

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

Confusion, eosinophilic pneumonia (a rare type of pneumonia), rhinitis (blocked up or runny nose), 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,

Reporting of side effects

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

5. How to store Perindopril tert-butylamine 8 mg tablets

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

Do not store above 25°C. Store in the original container.

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 tert-butylamine 8 mg tablets contains:

The active substance is perindopril tert-butylamine (each tablet contains 8 mg of perindopril tert-butylamine which is equivalent to 6.68 mg of perindopril).

The other ingredients are lactose monohydrate, microcrystalline cellulose, silica colloidal anhydrous and magnesium stearate.

What Perindopril tert-butylamine 8 mg tablets looks like and contents of the pack:

The 8 mg tablets are white to off-white, capsule-shaped, convex tablets embossed with 'PI | 8' on one side and '>' on the other side.

Perindopril tert-butylamine 8 mg tablets are available in blister packs containing 7, 10, 14, 15, 20, 28, 30, 50, 56, 60, 90, 100, 112, 120 and 500 tablets.

If the blisters are packed in a foil pouch, a desiccant is also enclosed. Do not swallow desiccant.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

Arrow Generics Limited,
Whiddon Valley, Barnstaple, Devon,
EX32 8NS
United Kingdom

Manufacturer:

Actavis Ltd, BLB 016, Bulebel Industrial Estate, Zejtun, ZTN 3000, Malta

or

Arrow Pharm (Malta) Limited, 62 Hal Far Industrial Estate, Birzebbugia, BBG06, Malta

or

Arrow Génériques SAS, 26 Avenue Tony Garnier, 69007 Lyon, Francija

or

Juta Pharma GmbH, Gutenbergstraße 13, 24941 Flensburg, Germany

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

France:	Perindopril Arrow 2 mg, 4 mg, 8 mg comprimé
Ireland:	Perindopril tert-butylamine 8 mg Tablets
Malta:	Perindopril 2 mg, 4 mg, 8 mg Tablets
Slovenia:	Percarnil
United Kingdom:	Perindopril 2 mg, 4 mg, 8 mg Tablet

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