Package leaflet: Information for the user

Perindopril Aurobindo 2 mg tablets
Perindopril Aurobindo 4 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Perindopril Aurobindo is and what it is used for

Perindopril Aurobindo 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 Aurobindo is used:
- to treat ***high blood pressure*** (hypertension),
- to treat ***heart failure*** (a condition where the heart is unable to pump enough blood to meet the body's needs),
- 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 Aurobindo

Do not take Perindopril Aurobindo
- if you are allergic to perindopril, or any of the other ingredients in this medicine (listed in section 6), or to any other ACE inhibitor.
- if you are more than 3 months pregnant. (It is also better to avoid Perindopril Aurobindo 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
- 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.
- If you are having dialysis or any other type of blood filtration. Depending on the machine that is used, perindopril may not be suitable for you,
- If you have kidney problems where the blood supply to your kidneys is reduced (renal artery stenosis),

Warnings and precautions
If any of the following apply to you please. talk to your doctor or pharmacist before taking Perindopril Aurobindo

- 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 have abnormally increased levels of a hormone called aldosterone in your blood (primary aldosteronism),
- if you suffer from a collagen vascular disease such as systemic lupus erythematosus or scleroderma,
- if you have diabetes,
- if you are on a salt restricted diet or use salt substitutes which contain potassium,
- if you are going to have a general anaesthetic and/or major surgery,
- 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 to bee or wasp stings,
- if you have recently suffered from diarrhoea or vomiting, or are dehydrated,
- 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 Aurobindo"

- if you are of black origin since you may have a higher risk of angioedema (rapid swelling under the skin in an area such as the throat) 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 (a medicine used to treat diarrhea)
  - medicines used to prevent organ transplant rejection and for cancer (e.g., temsirolimus, sirolimus, everolimus).
  - vildagliptin, a medicine used to treat diabetes.

- sacubitril (available as fixed-dose combination with valsartan), used to treat long-term heart failure.

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

Other medicines and Perindopril Aurobindo
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
Treatment with Perindopril Aurobindo can be affected by other medicines. Your doctor may need to change your dose and/or to take other precautions. These include:

- other medicines for high blood pressure, including angiotensin II receptor blocker (ARB) or aliskiren (see also information under the headings "Do not take Perindopril tert-butylamine Aurobindo" and "Warnings and precautions"), or diuretics (medicines which increase the amount of urine produced by the kidneys),
- 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).
- lithium for mania or depression,
- non-steroidal anti-inflammatory drugs (e.g. ibuprofen) for pain relief or high dose aspirin,
- medicines to treat diabetes (such as insulin or metformine),
- baclofen (used to treat muscle stiffness in diseases such as multiple sclerosis),
- medicines to treat mental disorders such as depression, anxiety, schizophrenia etc (e.g. tricyclic antidepressants, antipsychotics),
- 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, tacrolimus),
- trimethoprim (for the treatment of infections),
- estramustine (used in cancer therapy),
- 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"
- sacubitril/valsartan (used to treat long-term heart failure).See sections "Do not take Perindopril " and "Warnings and precautions",
- allopurinol (for the treatment of gout),
- procainamide (for the treatment of an irregular heart beat),
- vasodilators including nitrates (products that make the blood vessels become wider),
- heparin (medicines used to thin blood),
- medicines used for the treatment of low blood pressure, shock or asthma (e.g. ephedrine, noradrenaline or adrenaline).
- gold salts, especially with intravenous administration (used to treat symptoms of rheumatoid arthritis).

Perindopril Aurobindo with food and drink
It is preferable to take Perindopril Aurobindo before a meal.

Pregnancy, breast-feeding and fertility
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 Aurobindo before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Perindopril Aurobindo. Perindopril Aurobindo 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 Aurobindo 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 Aurobindo 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 Aurobindo 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 Aurobindo

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 is 4 mg once daily. After one month, this can be increased to 8 mg once a day if required. 8 mg a day 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.

Heart failure: the usual starting dose is 2 mg once daily. After two weeks, this can be increased to 4 mg once a day, which is the maximum recommended dose for heart failure.

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 Aurobindo 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 the legs raised can help.

If you forget to take Perindopril Aurobindo

It is important to take your medicine every day as regular treatment works better. However, if you forget to take a dose of Perindopril Aurobindo, 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 Aurobindo
As the treatment with Perindopril Aurobindo 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.
Stop taking the medicinal product and see a doctor immediately if you experience any of the following side effects that can be serious:

Common (may affect up to 1 in 10 people):
- severe dizziness or fainting due to low blood pressure,

Uncommon (may affect up to 1 in 100 people):
- swelling of the face, lips, mouth, tongue or throat, difficulty in breathing (angioedema) (See section 2 “Warning and precaution”),
- sudden wheeziness, chest pain, shortness of breath, or difficulty in breathing (bronchospasm),

Very rare (may affect up to 1 in 10,000 people)
- unusual fast or irregular heartbeat, chest pain (angina) or heart attack,
- weakness of arms or legs, or problems speaking which could be a sign of a possible stroke,
- 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,
- skin rash which often starts with red itchy patches on your face, arms or legs (erythema multiforme).

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 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,
- 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,
- depression

Rare (may affect up to 1 in 1,000 people):
- psoriasis worsening,
- changes in laboratory parameters: Increased level of liver enzymes, high level of serum bilirubin,

- 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).
- decreased or absent urine output
- flushing
- acute renal failure

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),
- changes in blood values such as a lower number of white and red blood cells, lower haemoglobin, lower number of blood platelets.

If you have these symptoms contact your doctor as soon as possible.

Not known (frequency cannot be estimated from available data):
- Discoloration, numbness and pain in fingers or toes (Raynaud's phenomenon).

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

ADR Reporting
Website:www.medicinesauthority.gov.mt/adrportal.
e-mail: postlicensing.medicinesauthority@gov.mt

5. How to store Perindopril Aurobindo

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

Store in the original package in order to protect from moisture and light.
Do not store above 25°C

Use within 60 days after first opening the aluminium pouch. Aluminium pouch contains desiccant, do not swallow the desiccant.

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 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 Aurobindo contains

- The active substance is perindopril tert-butylamine.
  Each tablet contains 2 mg of perindopril tert-butylamine, equivalent to 1.669 mg perindopril.
  Each tablet contains 4 mg of perindopril tert-butylamine, equivalent to 3.338 mg perindopril.

- The other ingredients are: Lactose, cellulose, microcrystalline (E460), silica colloidal anhydrous (E551), and magnesium stearate (E572).

What Perindopril Aurobindo looks like and contents of the pack

Perindopril Aurobindo 2 mg tablets

White to off-white coloured, round biconvex, uncoated tablets with debossing "D" on one side and "57"on the other side.

Perindopril Aurobindo 4mg tablets

White to off-white coloured, capsule shaped, uncoated tablets with debossing "D" on one side and "5" & "8" on either side of the break line on another side. The tablet can be divided into two equal halves.

Perindopril Aurobindo tablets are available in blister packs of 28, 30, 56, 60, 84, 90, 112 and 120 tablets

The blisters are packed in a foil pouch containing a desiccant. Each foil pouch contains 28 or 30 tablets. Do not swallow desiccant.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Aurobindo Pharma (Malta) Limited
Vault 14, Level 2, Valletta Waterfront
Floriana FRN 1913
Malta

Manufacturer

APL Swift Services (Malta) Limited
HF26, Hal Far Industrial Estate, Hal Far,
Birzebbugia, BBG 3000.
Malta

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

France:	Perindopril Arrow Lab 2 mg, comprimé
	Perindopril Arrow Lab 4 mg, comprimé sécable
Malta:	Perindopril Aurobindo 2 mg/ 4 mg Tablets
The Netherlands	Perindopril tert-butylamine Aurobindo 2 mg/ 4 mg, tabletten
Poland	PERINDANOR
Spain	Perindopril Aurovitas 4 mg comprimidos EFG
United kingdom	Perindopril 2 mg/ 4 mg tablets

This leaflet was last revised in March 2023.