Package leaflet: Information for the patient

Perindopril Arginine Clonmel 2.5 mg film-coated tablets
Perindopril Arginine Clonmel 5 mg film-coated tablets
Perindopril Arginine Clonmel 10 mg film-coated tablets
perindopril arginine

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 Arginine Clonmel is and what it is used for
2. What you need to know before you take Perindopril Arginine Clonmel
3. How to take Perindopril Arginine Clonmel
4. Possible side effects
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1. What Perindopril Arginine Clonmel is and what it is used for

Perindopril Arginine Clonmel 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 Arginine Clonmel 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) (only Perindopril Arginine Clonmel 2.5 mg and 5 mg).
- 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 Arginine Clonmel

Do not take Perindopril Arginine Clonmel
- if you are allergic to perindopril, any other ACE inhibitor 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, 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 are more than 3 months pregnant (It is also better to avoid Perindopril Arginine Clonmel in early pregnancy – see pregnancy section).
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.
- if you are having dialysis or any other type of blood filtration. Depending on the machine that is used, Perindopril Arginine Clonmel may not be suitable for you.
- if you have kidney problems where the blood supply to your kidneys is reduced (renal artery stenosis).

– 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 (see "Warnings and Precautions" and "Other medicines and Perindopril Arginine Clonmel").

Warnings and precautions
Talk to your doctor or pharmacist before taking Perindopril Arginine Clonmel 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).
– have any other heart problems.
– have liver problems.
– have kidney problems or if you are receiving dialysis.
– have abnormally increased levels of a hormone called aldosterone in your blood (primary aldosteronism).
– suffer from a collagen vascular disease (disease of the connective tissue) such as systemic lupus erythematosus or scleroderma.
– have diabetes.
– are on a salt restricted diet or use salt substitutes which contain potassium.
– are to undergo anaesthesia and/or major surgery.
– are to undergo LDL apheresis (which is removal of cholesterol from your blood by a machine),
– are going to have desensitisation treatment to reduce the effects of an allergy to bee or wasp stings.
– have recently suffered from diarrhoea or vomiting, or are dehydrated.
– 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 Arginine Clonmel".
– 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.
– are taking any of the following medicines, the risk of angioedema (rapid swelling under the skin in area such as the throat) is increased:
  • Racecadotril, a medicine used to treat diarrhoea.
  • Medicines used to prevent organ transplant rejection and for cancer (e.g. temsirolimus, sirolimus, everolimus) and other medicines belonging to the class of so-called mTOR inhibitors.
  • Sacubitril (available as fixed-dose combination with valsartan), used to treat long-term heart failure.
  • Linagliptin, saxagliptin, sitagliptin, vildagliptin and other medicines belonging to the class of the so-called gliptins (used to treat diabetes).

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 arginine. This may occur at any time during treatment. If you develop such symptoms, you should stop taking Perindopril Arginine Clonmel and see a doctor immediately. See also section 4.
You must tell your doctor if you think you are (or might become) pregnant. Perindopril Arginine Clonmel 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 Arginine Clonmel
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Treatment with Perindopril Arginine Clonmel 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), aliskiren (see also information under the headings "Do not take Perindopril Arginine Clonmel" and "Warnings and precautions"), or diuretics (medicines which increase the amount of urine produced by the kidneys).
- potassium-sparing medicines (e.g. triamterene, amiloride), potassium supplements or potassium-containing salt substitutes other medicines that can increase potassium in your body (such as heparin, a medicine used to thin blood to prevent clots; trimethoprim and co-trimoxazole also known as trimethoprim/sulfamethoxazole for infections caused by bacteria.
- Potassium-sparing medicines used in the treatment of heart failure: eplerenone and spironolactone at doses between 12.5 mg to 50 mg by day.
- Lithium for mania or depression.
- Non-steroidal anti-inflammatory drugs (e.g. ibuprofen) for pain relief or high dose acetylsalicylic acid, a substance present in many medicines used to relieve pain and lower fever, as well as to prevent blood clotting.
- Medicines to treat diabetes (such as insulin or metformin).
- 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 diarrhoea (racecadotril).
- Medicines, which are most often used to 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".
- Sacubitril/valsartan (used to treat long-term heart failure). See sections "Do not take Perindopril Arginine Clonmel" and "Warnings and precautions".
- Allopurinol (for the treatment of gout).
- Procainamide (for the treatment of an irregular heartbeat).
- Vasodilators including nitrates (products that make the blood vessels become wider).
- 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 Arginine Clonmel with food and drink
It is preferable to take Perindopril Arginine Clonmel 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 Arginine Clonmel before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Perindopril Arginine Clonmel. Perindopril Arginine Clonmel 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 Arginine Clonmel 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 new-born, or was born prematurely.

Driving and using machines
Perindopril arginine 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 Arginine Clonmel contains lactose monohydrate and sodium
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially "sodium-free".

3. How to take Perindopril Arginine Clonmel

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 5 mg once daily. After 1 month, this can be increased to 10 mg once a day if required. 10 mg a day is the maximum recommended dose for high blood pressure.
If you are 65 or older, the usual starting dose is 2.5 mg once a day. After a month this can be increased to 5 mg once a day and then if necessary to 10 mg once daily.

Heart failure (only Perindopril Arginine Clonmel 2.5 mg and 5 mg)**:** the usual starting dose is 2.5 mg once daily. After 2 weeks, this can be increased to 5 mg once a day, which is the maximum recommended dose for heart failure.

Stable coronary artery disease: the usual starting dose is 5 mg once daily. After 2 weeks, this can be increased to 10 mg once daily, which is the maximum recommended dose in this indication.
If you are 65 or older, the usual starting dose is 2.5 mg once a day. After a week this can be increased to 5 mg once a day and after a further week to 10 mg once daily.

Use in children and adolescents
Use in children and adolescent is not recommended.

If you take more Perindopril Arginine Clonmel 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 Arginine Clonmel
It is important to take your medicine every day as regular treatment works better. However, if you forget to take a dose of Perindopril Arginine Clonmel, 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 Arginine Clonmel
As the treatment with Perindopril Arginine Clonmel 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, pharmacist or nurse.

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:
- Swelling of the face, lips, mouth, tongue or throat, difficulty in breathing (angioedema) (see section 2 "Warnings and precautions") (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 heartbeat, 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 (inflammation of the liver) (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 (feeling dizzy with a spinning sensation).
- 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 tiredness.

Uncommon (may affect up to 1 in 100 people):
- Mood swings.
- Sleep disturbances.
- Depression.
- 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 (rapid heartbeat).
- Vasculitis (inflammation of blood vessels).
- Photosensitivity reaction (increased sensitivity of the skin to sun).
- Arthralgia (joint pain).
- Myalgia (muscle pain).
- Chest pain.
- Malaise (feeling generally unwell).
- Oedema peripheral (swelling of your legs or hands).
- 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):
- 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.
- Psoriasis worsening.
- Decreased or absent urine output.
- Acute renal failure,
- Changes in laboratory parameters: increased level of liver enzymes, high level of serum bilirubin.

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.

Not known (frequency cannot be estimated from the 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 via:
Ireland:
HPRA Pharmacovigilance
Website: www.hpra.ie.

Malta:
ADR Reporting
Website: www.medicinesauthority.gov.mt/adrportal
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Perindopril Arginine Clonmel

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

Perindopril Arginine Clonmel 2.5 mg: Store below 25 °C.
Perindopril Arginine Clonmel 5 mg and 10 mg: Store below 25 °C in the original package in order to protect from light.
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 Arginine Clonmel contains

- The active substance is perindopril arginine. Perindopril Arginine Clonmel 2.5 mg: Each film-coated tablet contains 2.5 mg perindopril arginine equivalent to 1.6975 mg perindopril. Perindopril Arginine Clonmel 5 mg: Each film-coated tablet contains 5 mg perindopril arginine equivalent to 3.395 mg perindopril.Perindopril Arginine Clonmel 10 mg: Each film-coated tablet contains 10 mg perindopril arginine equivalent to 6.790 mg perindopril.
- The other ingredients are: lactose monohydrate, starch pregelatinized, sodium starch glycolate, silica hydrophobic colloidal, magnesium stearate, hypromellose, calcium carbonate, macrogol 3350, triglycerides, medium chain , talc Perindopril Arginine Clonmel 2.5 mg: carmellosum, citric acid, Perindopril Arginine Clonmel 5 mg and 10 mg: quinoline yellow aluminium lake (E104), iron oxide yellow (E172), brilliant blue FCF aluminium lake (E133), iron oxide black (E172).

What Perindopril Arginine Clonmel looks like and contents of the pack
Perindopril Arginine Clonmel 2.5 mg: White to off-white, rounded, convex film-coated tablet of diameter 5.0 ± 0.25 mm.
Perindopril Arginine Clonmel 5 mg: Light-green, oval, biconvex film-coated tablet with length 10.0 ± 0.50 mm and width 4.75 ± 0.24 mm with both-sided scoring line. The tablet can be divided into equal doses.
Perindopril Arginine Clonmel 10 mg: Green to marble green, rounded, biconvex film-coated tablet of diameter 9.0 ± 0.45 mm with one-sided debossing “10”.
Perindopril Arginine Clonmel is available in OPA/Alu/PVC//Alu or PVC/PVDC white//Alu blisters.

Pack sizes:
Perindopril Arginine Clonmel 2.5 mg: 30 or 90 film-coated tablets.
Perindopril Arginine Clonmel 5 mg: 15, 30 or 90 film-coated tablets.
Perindopril Arginine Clonmel 10 mg: 30 or 90 film-coated tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing authorisation holder
Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

Manufacturer
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This medicine is authorised in the Member States of the European Economic Area under the following names:

Czech Republic:	Perindopril Arginine STADA Arzneimittel AG
Belgium:	Perindopril EG 2,5 mg filmomhulde tabletten, Perindopril EG 5 mg filmomhulde tabletten, Perindopril EG 10 mg filmomhulde tabletten
Luxembourg:	Perindopril EG 2,5 mg comprimés pelliculés, Perindopril EG 5 mg comprimés pelliculés, Perindopril EG 10 mg comprimés pelliculés
Ireland:	Perindopril Arginine Clonmel 2.5 mg film-coated tablets

	Perindopril Arginine Clonmel 2.5 mg film-coated tablets
Malta:	Perindopril Arginine Clonmel 5 mg film-coated tablets
	Perindopril Arginine Clonmel 10 mg film-coated tablets

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