

Package leaflet: Information for the patient

Perindopril arginine Mylan 2.5 mg film-coated tablets

Perindopril arginine Mylan 5 mg film-coated tablets

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

1. What Perindopril arginine Mylan is and what it is used for

Perindopril arginine Mylan belongs to a group of medicines known as angiotensin converting enzyme (ACE) inhibitors. These work by making your blood vessels wider, which makes it easier for your heart to pump blood through them.

Perindopril arginine Mylan 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) *[for 2.5 mg & 5 mg only]*
- 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.

2. What you need to know before you take Perindopril arginine Mylan

Do not take Perindopril arginine Mylan

- 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 have taken or are currently taking sacubitril/valsartan, a medicine used to treat a type of long term (chronic) heart failure in adults, the risk of angioedema (rapid swelling under the skin in an area such as the throat) is increased. Treatment with sacubitril/valsartan must not be initiated earlier than 36 hours after taking the last dose of Perindopril arginine Mylan. Treatment with Perindopril arginine Mylan must not be initiated earlier than 36 hours after the last dose of sacubitril/valsartan. (See sections "Warnings and precautions" and "Other medicines and Perindopril arginine Mylan").
- if you are having dialysis or any other type of blood filtration. Depending on the machine that is used, Perindopril arginine Mylan 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 are more than 3 months pregnant (It is also better to avoid Perindopril arginine Mylan in early pregnancy - see pregnancy section).
- Perindopril arginine Mylan contains soya oil. If you are allergic to peanut or soya do not use this medicinal product.
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.

Warnings and precautions

If any of the following apply to you please talk to your doctor or pharmacist before taking Perindopril arginine Mylan:

- 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,
- have been told by your doctor that you have an intolerance to some sugars.
- 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 Mylan"

- 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 may be increased:
 - racecadotril a medicine used to treat diarrhoea

- medicines used to prevent organ transplant rejection and for cancers (e.g. temsirolimus, sirolimus, everolimus)
- vildagliptin, a medicine used to treat diabetes
- sacubitril/valsartan (used to treat long-term heart failure). See section "Do not take Perindopril arginine Mylan".

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 Mylan. This may occur at any time during treatment. If you develop such symptoms, you should stop taking Perindopril arginine Mylan and see a doctor immediately. See also section 4.

You must tell your doctor if you think that you are (or might become) pregnant. Perindopril arginine Mylan 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

Perindopril arginine Mylan is not recommended for use in children and adolescents up to the age of 18 years.

Other medicines and Perindopril arginine Mylan

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Perindopril arginine Mylan can affect the way some other medicines work and some medicines can have an effect on Perindopril arginine Mylan. In particular, tell your doctor if you are using any of the following medicines:

- other medicines for high blood pressure, including diuretics (medicines which increase the amount of urine produced by the kidneys),
- potassium supplements (including salt substitutes), potassium-sparing diuretics (e.g. triamterene or amiloride) 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),
- potassium-sparing drugs used in the treatment of heart failure: eplerenone and spironolactone at doses between 12.5 mg to 50 mg per day,
- lithium (a medicine for mental health problems),
- non-steroidal anti-inflammatory drugs (e.g. ibuprofen) for pain relief or high dose aspirin,
- 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 or schizophrenia (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 for the treatment of gout (e.g. allopurinol),
- medicines for the treatment of an irregular heart beat (e.g. procainamide),
- products that make the blood vessels become wider (e.g. vasodilators including nitrates),

- 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).

Treatment with Perindopril arginine Mylan can be affected by other medicines. Your doctor may need to change your dose and/or to take other precautions. These include:

- if you are taking an angiotensin II receptor blocker (ARB) or aliskiren (see also information under the headings "Do not take Perindopril arginine Mylan" and "Warnings and precautions").
- sacubitril/valsartan (a medicine used to treat a type of long term (chronic) heart failure is contraindicated (see section "Do not take Perindopril arginine Mylan")
Treatment with sacubitril/valsartan must not be initiated earlier than 36 hours after taking the last dose of perindopril arginine therapy. Treatment with perindopril arginine must not be initiated earlier than 36 hours after the last dose of sacubitril/valsartan.

Perindopril arginine Mylan with food and drink

It is recommended to take Perindopril arginine Mylan 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 Mylan 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 Mylan. Perindopril arginine Mylan 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 Mylan 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.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Perindopril arginine Mylan 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 operate machinery may be impaired.

Perindopril arginine Mylan contains lactose, sodium and soya oil

If you have been told by your doctor that you have an intolerance to some sugars, such as lactose, contact your doctor before taking this medicine.

If you are allergic to peanut or soya do not use this medicine (see 'Do not take Perindopril arginine Mylan').

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 Mylan

Always take this medicine exactly as your doctor 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 dose for Perindopril arginine Mylan is:

High blood pressure:

The recommended starting and maintenance dose is 5 mg once daily. After one 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 years old or older, treatment usually starts with 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: *[for 2.5 mg & 5 mg only]*

The recommended dose is 2.5 mg once daily. After two 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 recommended starting dose is 5 mg once daily. After two weeks, this can be increased to 10 mg once a day, which is the maximum recommended dose for this indication.

If you are 65 years old or older, the recommended 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 adolescents is not recommended.

If you take more Perindopril arginine Mylan than you should

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 your legs raised can help.

If you forget to take Perindopril arginine Mylan

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 Mylan, 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 Mylan

As the treatment with Perindopril arginine Mylan 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.

If you experience any of the following, **stop taking the medicinal product at once** and tell your doctor immediately:

- 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)
- sudden wheeziness, chest pain, shortness of breath, or difficulty in breathing (bronchospasm) (Uncommon - may affect up to 1 in 100 people)
- severe skin disease with blisters and sores (pemphigoid) (Uncommon - may affect up to 1 in 100 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)
- 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).

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)
- gastrointestinal disorders (nausea, vomiting, abdominal pain, taste disturbances, dyspepsia or difficulty of digestion, diarrhoea, constipation)
- allergic reactions (such as skin rashes, itching)
- muscle cramps
- tiredness.

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

- mood swings, sleep disturbances
- dry mouth
- intense itching or severe skin rashes)
- kidney problems
- impotence
- sweating
- changes in blood test results including increase in potassium (hyperkalaemia, reversible on discontinuing medicine), low levels of sodium, very low blood sugar level in case of diabetic patients (hypoglycaemia), increase in blood urea and increased creatinine
- feeling sleepy (somnolence)
- fainting
- palpitations
- fast heartbeat (tachycardia)
- excessive sweating (hyperhidrosis)

- sensitivity of the skin to light (photosensitivity)
- muscle pain (myalgia)
- joint soreness and pain (arthralgia)
- chest pain
- malaise
- fever
- falls
- oedema peripheral
- vasculitis (inflammation of blood vessels)
- excess of eosinophils (a type of white blood cells).

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.

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.

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

Not known (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 via HPRA Pharmacovigilance. Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Perindopril arginine Mylan

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

This medicine does not require any special storage conditions.

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 Mylan contains

The active substance is perindopril arginine.

One 2.5 mg tablet contains 2.5 mg of perindopril arginine, equivalent to 1.6975 mg of perindopril.

One 5 mg tablet contains 5 mg of perindopril arginine, equivalent to 3.395 mg of perindopril.

One 10 mg tablet contains 10 mg of perindopril arginine, equivalent to 6.790 mg of perindopril.

The other ingredients are:

Core:

Lactose monohydrate (see section 2 'Perindopril arginine Mylan contains lactose, sodium and soya oil'), Magnesium stearate, Maltodextrin, Silica hydrophobic colloidal, Sodium starch glycolate (type A), Povidone (K 30).

Film-coating: *[for 2.5 mg only]*

Lecithin (Soya) (E322) (see section 2 'Perindopril arginine Mylan contains lactose, sodium and soya oil'), Polyvinyl alcohol, Talc (E553b), Titanium dioxide (E171), Xanthan gum (E415).

Film-coating: *[for 5 mg & 10 mg only]*

Lecithin (Soya) (E322) (see section 2 'Perindopril arginine Mylan contains lactose, sodium and soya oil'), Polyvinyl alcohol, Talc (E553b), Titanium dioxide (E171), Xanthan gum (E415), Quinoline yellow aluminium lake (E104), FD & C Blue no 1/Brilliant blue FCF aluminium lake (E133), Iron oxide yellow (E172).

What Perindopril arginine Mylan looks like and contents of the pack

Perindopril arginine Mylan 2.5 mg film-coated tablets are white, round, biconvex, film-coated tablets debossed with "PA" over "1" on one side and "M" on the other side.

Perindopril arginine Mylan 5 mg film-coated tablets are green capsule shaped, biconvex, film-coated tablets with side notch, debossed with "PA2" on one side and "M" on the other side. The tablet can be divided into equal doses.

Perindopril arginine Mylan 10 mg film-coated tablets are green, round, biconvex, film-coated tablets debossed with "PA3" on one side and "M" on the other side.

Perindopril arginine Mylan is available in blisters of 10, 14, 30, 60, 90 and 100 tablets and in plastic bottles of 30, 60, 90 and 100 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

McDermott Laboratories Ltd. T/A Gerard Laboratories
35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland

Manufacturer:

McDermott Laboratories Ltd. T/A Gerard Laboratories
35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.

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

Belgium:	Perindargmylan filmomhulde tabletten
Czech Republic:	Perindopril Arginin Mylan potahované tablety
France:	Perindopril Arginine Mylan comprimé pelliculé
Ireland:	Perindopril arginine Mylan film-coated tablets
Italy:	Perindopril Mylan Generics
Luxembourg:	Perindargmylan comprimés pelliculés
The Netherlands:	Perindopril arginine Mylan filmomhulde tabletten
Poland:	Presomyl
Portugal:	Perindopril Mylan
Romania:	Perindopril arginină Mylan comprimate filmate
Slovenia:	Perindopril Mylan filmsko obložene tablete
Slovakia:	Perindopril Arginin Mylan
United Kingdom:	Perindopril arginine film-coated tablets

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