

Package leaflet: Information for the patient

Perindopril Arginine/Indapamide Mylan 2.5 mg/0.625 mg film-coated tablets Perindopril Arginine/Indapamide Mylan 5 mg/1.25 mg film-coated tablets perindopril arginine and indapamide

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

Perindopril Arginine/Indapamide Mylan is a combination of two active ingredients, perindopril and indapamide. It is an anti-hypertensive and is used in the treatment of high blood pressure (hypertension).

Perindopril belongs to a group of medicines known as angiotensin converting enzyme (ACE) inhibitors, which widen the blood vessels, and therefore it is easier for the heart to pump blood through them. Indapamide is a diuretic, which is a type of medicine that increases the amount of urine produced by the kidneys. These two active ingredients work together to reduce and control your blood pressure.

2. What you need to know before you take Perindopril Arginine/Indapamide Mylan

Do not take Perindopril Arginine/Indapamide Mylan:

- if you are allergic to perindopril or any other ACE inhibitor, indapamide or any other sulphonamides, or any of the other ingredients of this medicine (listed in section 6),
- if you have ever experienced symptoms such as wheezing, swelling of the face or tongue, 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 severe liver disease or suffer from a condition called hepatic encephalopathy (degenerative disease of the brain),
- if you have a severe kidney disease or if you are receiving dialysis,
- if you have low or high blood potassium,
- if you are suspected of having untreated decompensated heart failure (severe water retention, difficulty in breathing),
- if you are more than 3 months pregnant (It is better to avoid Perindopril Arginine/Indapamide Mylan see 'Pregnancy and breast-feeding'),

- if you are breast-feeding,
- Perindopril Arginine/Indapamide 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

Talk to your doctor or pharmacist before taking Perindopril Arginine/Indapamide Mylan

- 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 or problems with your kidneys,
- if you have liver problems,
- if you suffer from a collagen disease (skin disease) such as systemic lupus erythematosus or scleroderma,
- if you have atherosclerosis (hardening of the arteries),
- if you suffer from hyperparathyroidism (overactive parathyroid gland),
- if you suffer from gout,
- if you have diabetes,
- if you are on a salt restricted diet or use salt substitutes which contain potassium,
- if you take lithium or potassium-sparing diuretics (spironolactone, triamterene) as their use with Perindopril Arginine/Indapamide Mylan should be avoided (see ‘Taking other medicines’).
- 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
- if you are taking any of the following medicines, the risk of angioedema is increased:
 - racecadotril (used to treat diarrhoea)
 - sirolimus, everolimus, temsirolimus and other drugs belonging to the class of so-called mTor inhibitors (used to avoid rejection of transplanted organs)

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/Indapamide Mylan”

You must tell your doctor if you think that you are (or might become) pregnant. Perindopril Arginine/Indapamide 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 and breast-feeding’).

When you are taking Perindopril Arginine/Indapamide Mylan, you should also inform your doctor or the medical staff:

- if you are to undergo anaesthesia and/or surgery,
- if you have recently suffered from diarrhoea or vomiting, or are dehydrated,
- if you are to undergo dialysis or 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 are to undergo a medical test that requires injection of an iodinated contrast agent (a substance that makes organs like kidney or stomach visible on an X-ray)

Athletes should be aware that Perindopril Arginine/Indapamide Mylan contains an active ingredient (indapamide) which may give a positive reaction in drug tests.

Perindopril Arginine/Indapamide Mylan should not be given to children.

Other medicines and Perindopril Arginine/Indapamide 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.

Do not take Perindopril Arginine/Indapamide Mylan if you are taking the following:

- lithium (for the treatment of depression),
- potassium-sparing diuretics (e.g. spironolactone or triamterene), or potassium salts.

Treatment with Perindopril Arginine/Indapamide Mylan can be affected by other medicines. Make sure to tell your doctor if you are taking any of the following medicines as special care may be required:

- other medicines for treating high blood pressure,
- procainamide (for the treatment of an irregular heart beat),
- allopurinol (for the treatment of gout),
- terfenadine or astemizole (antihistamines for hay fever or allergies),
- corticosteroids used to treat various conditions including severe asthma and rheumatoid arthritis,
- immunosuppressants used for the treatment of auto-immune disorders or following transplant surgery to prevent rejection (e.g. ciclosporin),
- medicines for the treatment of cancer,
- erythromycin by injection (an antibiotic),
- halofantrine (used to treat certain types of malaria),
- pentamidine (used to treat pneumonia),
- injectable gold (used in the treatment of rheumatoid polyarthritis),
- vincamine (used to treat symptomatic cognitive disorders in elderly including memory loss),
- bepridil (used to treat angina pectoris),
- sultopride (for the treatment of psychoses),
- medicines used for heart rhythm problems (e.g. quinidine, hydroquinidine, disopyramide, amiodarone, sotalol),
- digoxin or other cardiac glycosides (for the treatments of heart problems),
- baclofen (to treat muscle stiffness occurring in diseases such as multiple sclerosis),
- medicines to treat diabetes such as insulin or metformin,
- calcium including calcium supplements,
- stimulant laxatives (e.g. senna),
- non-steroidal anti-inflammatory drugs (e.g. ibuprofen) or high dose salicylates (e.g. aspirin),
- amphotericin B by injection (to treat severe fungal disease),
- medicines to treat mental disorders such as depression, anxiety or schizophrenia... (e.g. tricyclic antidepressants or neuroleptics),
- tetracosactide (to treat Crohn's disease).

Treatment with Perindopril Arginine/Indapamide 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/Indapamide Mylan” and “Warnings and precautions”).
- medicines, which is most often used to treat diarrhoea (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”.

Taking Perindopril Arginine/Indapamide Mylan with food and drink

It is preferable to take Perindopril Arginine/Indapamide 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 that you are (or might become) pregnant. Your doctor will normally advise you to stop taking Perindopril Arginine/Indapamide 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/Indapamide Mylan. Perindopril Arginine/Indapamide 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

You must not take Perindopril Arginine/Indapamide Mylan if you are breast-feeding. Tell your doctor immediately if you are breast-feeding or about to start breast-feeding.

Driving and using machines

Perindopril Arginine/Indapamide Mylan usually does not affect alertness, but different reactions such as dizziness or weariness in relation to the decrease in blood pressure may occur in certain patients. If affected, your ability to drive or operate machinery may be impaired.

Perindopril Arginine/Indapamide Mylan contains lactose 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.

3. How to take Perindopril Arginine/Indapamide Mylan

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is one tablet once a day. Your doctor may decide to increase the dose to 2 tablets daily or to modify the dosage regimen if you suffer from renal impairment. Take your tablet preferably in the morning and before a meal. Swallow the tablet with a glass of water.

If you take more Perindopril Arginine/Indapamide than you should

If you take too many tablets, contact your doctor or nearest hospital casualty department **immediately**. The most likely effect in case of overdose is low blood pressure. If marked low blood pressure occurs (symptoms such as dizziness or fainting), lying down with the legs raised can help.

If you forget to take Perindopril Arginine/Indapamide 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/Indapamide Mylan

As the treatment for high blood pressure 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,
- severe dizziness or fainting,
- unusually fast or irregular heart beat.

In decreasing order of frequency, side effects can include:

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

- headache, feelings of dizziness, vertigo, light-headedness due to low blood pressure,
- vision disturbances,
- tinnitus (sensation of noises in the ears),
- cough, shortness of breath,
- gastro-intestinal disorders (nausea, epigastric pain, anorexia, vomiting, abdominal pain, taste disturbances, dry mouth, dyspepsia or difficulty of digestion, diarrhoea, constipation),
- allergic reactions (such as skin rashes, itching),
- cramps, pins and needles,
- feeling of tiredness.

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

- mood swings, sleep disturbances,
- bronchospasm (tightening of the chest, wheezing and shortness of breath),
- angiodema (symptoms such as wheezing, swelling of the face or tongue),
- purpura (red pinpoint on skin), urticaria,
- kidney problems,
- impotence,
- sweating.

Rare (may affect up to 1 in 1,000 people):

- psoriasis worsening

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

- confusion,
- cardiovascular disorders (irregular heart beat, angina, heart attack),
- eosinophilic pneumonia (a rare type of pneumonia),
- rhinitis (blocked up or runny nose),
- severe skin manifestations such as erythema multiforme,
- if you suffer from systemic lupus erythematosus (a type of collagen disease), this might get worse,
- cases of photosensitivity reactions (change in skin appearance) after exposure to the sun or artificial UVA have also been reported,

- disorders of the blood, kidney, liver or pancreas and changes in laboratory parameters (blood tests) can occur,
- your doctor may need to give you blood tests to monitor your condition,
- in cases of hepatic insufficiency (liver problems), there is a possibility of onset of hepatic encephalopathy (degenerative disease of the brain).

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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Perindopril Arginine/Indapamide 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 bottle, carton or blister after 'EXP'. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Perindopril Arginine/Indapamide Mylan supplied in bottles should be used for no longer than 6 months after the bottle has first been opened.

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/Indapamide Mylan contains

The active substances are perindopril arginine and indapamide. One tablet contains 2.5 mg of perindopril arginine and 0.625 mg of indapamide or 5 mg of perindopril arginine and 1.25 mg of indapamide.

The other ingredients are:

Core:

Silica, hydrophobic colloidal, lactose monohydrate, magnesium stearate, maltodextrin, povidone (K 30), sodium starch glycolate (Type A).

Film-coating (Opadry AMB White OY-B-28920):

Lecithin (Soya) (E322), polyvinyl alcohol, talc (E553b), titanium dioxide (E171), xanthan gum (E415).

What Perindopril Arginine/Indapamide looks like and contents of the pack

Perindopril Arginine/Indapamide Mylan 2.5 mg/0.625 mg film-coated tablets are white, capsule shaped, biconvex, film-coated tablets debossed with a 'P', score line and 'I' on one side and an 'M', score line and '1' on the other side.

Perindopril Arginine/Indapamide Mylan 5 mg/1.25 mg film-coated tablets are white, capsule shaped, biconvex, film-coated tablets debossed with a 'PI' on one side and 'M2' on the other side.

Perindopril Arginine/Indapamide Mylan 2.5 mg/0.625 mg is available in blisters of 10, 14, 30, 60, 90 and 100 film-coated tablets and in a plastic bottle of 30 film-coated tablets. Not all pack sizes may be marketed.

Perindopril Arginine/Indapamide Mylan 5 mg/1.25 mg is available in blisters of 10, 14, 30, 60, 90 and 100 film-coated tablets and in a plastic bottle of 30 film-coated 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	Perinargindapamylan filmomhulde tabletten
Denmark	Pergindamyl filmoverttrukne tabletter
Finland	Pergindamyl kalvopäällysteiset tabletit
France	Perindopril Arginine Indapamide Mylan comprimé pelliculé
Germany	Perindopril-Arginin comp dura Filmtabletten
Hungary	Perindopril AS PreCombo/Perindopril AS Combo
Ireland	Perindopril Arginine/Indapamide Mylan film-coated tablets
Italy	Perindopril e Indapamide Mylan
Luxembourg	Perindapamylan comprimés
Poland	Co-Presomyl/Co-Presomyl Forte
Portugal	Perindopril + Indapamida Mylan
Romania	Perindopril/Indapamidă comprimate filmate
Slovakia	Perimyl Arginin Combi Filmom obalené tablety
Slovenia	Perindopril/indapamid Mylan filmsko obložene tablete
Netherlands	Perindopril arginine/Indapamide Mylan filmomhulde tabletten
United Kingdom	Perindopril arginine/Indapamide film-coated tablets

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