

Package leaflet: Information for the user

Perindopril arginine Actavis 5 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

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2. What you need to know before you take Perindopril arginine Actavis
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1. What Perindopril arginine Actavis is and what it is used for

Perindopril arginine Actavis 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 Actavis 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 arginine Actavis

Do not take Perindopril arginine Actavis

- if you are allergic to perindopril, to 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 Actavis 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

Warnings and precautions

Talk to your doctor or pharmacist before taking Perindopril arginine Actavis

- 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 (disease of the connective tissue) 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 to undergo anaesthesia 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 desensitization 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 arginine Actavis”.
- if you 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 (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 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.

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 Actavis. This may occur at any time during treatment. If you develop such symptoms, you should stop taking Perindopril arginine Actavis 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 Actavis 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 Actavis

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

Treatment with Perindopril arginine Actavis can be affected by other medicines. 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 arginine Actavis” and “Warnings and precautions” or diuretics (medicines which increase the amount of urine produced by the kidneys)
- potassium-sparing drugs (e.g. triamterene, amiloride), potassium supplements or potassium-containing salt substitutes, other drugs which can increase potassium in your body:
 - heparin (medicines used to thin blood)

- trimethoprim and co-trimoxazole also known as trimethoprim/sulfamethoxazole (for the treatment of infections)
- potassium-sparing drugs used in treatment of heart failure: eplerenone and spironolactone at doses between 12.5 mg to 50 mg per day
- 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 metformin)
- baclofen (used to treat muscle stiffness on diseases such as multiple sclerosis)
- medicines to treat mental disorders such as depression, anxiety, schizophrenia etc. (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”
- 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)
- estramustine (used in cancer therapy)
- 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 rheumatoid polyarthritis)

Perindopril arginine Actavis with food and drink

It is preferable to take Perindopril arginine Actavis 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 that you are (or might become) pregnant. Your doctor will normally advise you to stop taking Perindopril arginine Actavis 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 Actavis. Perindopril arginine Actavis 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 Actavis 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 arginine Actavis 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 Actavis 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 arginine Actavis

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.

Perindopril arginine Actavis 5 mg tablets can be divided into equal doses.

The recommended dosages are as follows:

High blood pressure: the usual 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 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: the usual starting 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 usual starting dose is 5 mg once daily. After two 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 adolescents is not recommended.

If you take more Perindopril arginine Actavis 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 Actavis

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 Actavis, 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 Actavis

As the treatment with Perindopril arginine Actavis 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:

- swelling of the face, lips, mouth, tongue or throat, difficulty in breathing (angioedema) (see section 3 "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 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 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):

- dizziness,
- headache,
- pins and needles,
- vertigo,
- 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,
- feeling of weakness.

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

- excess of eosinophils (a type of white blood cells),
- change in laboratory parameters: hypoglycaemia (very low blood sugar level) in case of diabetic patients, high blood level of potassium reversible on discontinuation, low level of sodium, increased blood urea, and increased blood creatinine.
- mood swings,
- sleep disturbances,
- somnolence,
- fainting,
- palpitations,
- tachycardia,
- vasculitis (inflammation of blood vessels),
- dry mouth,
- photosensitivity reaction (increased sensitivity of the skin to sun),
- formation of blister clusters over the skin,
- sweating,
- arthralgia (joint pain),
- myalgia (muscle pain),
- kidney problems,
- impotence,
- chest pain,
- malaise,
- oedema peripheral,
- fever,
- intense itching or severe skin rashes,
- fall,

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):

- changes in blood values such as a lower number of white and red blood cells, lower haemoglobin, lower number of blood platelets.
- confusion,
- eosinophilic pneumonia (a rare type of pneumonia),
- rhinitis (blocked up or runny nose),
- acute renal failure.

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 via [the national reporting system](#) listed in [Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Perindopril arginine Actavis

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

Blisters: Do not store above 30°C. Store in original package in order to protect from moisture.

Tablet container: Keep the bottle tightly closed in order to protect from moisture.

Do not use this medicine after the expiry date which is stated on the label, carton or bottle 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 arginine Actavis contains

- The active substance is perindopril arginine. Each tablet contains 5 mg perindopril arginine.
- The other ingredients are:
Tablet core: Magnesium stearate, silica, hydrophobic colloidal, sodium starch glycolate (type A), glycerol dibehenate, maltodextrin, lactose monohydrate
Film-coating: Polyvinyl alcohol-part. hydrolyzed (E1203), titanium dioxide (E171), macrogol (E1521), talc (E553b)

What Perindopril arginine Actavis looks like and contents of the pack

Perindopril arginine Actavis 5 mg film-coated tablets are white, oval, biconvex with side score and with two dots on one side. The tablet can be divided into equal doses.

The tablet container contains a desiccant, do not eat the desiccant

Pack sizes:

Blister packs (OPA/Al/PVC/Al): 5, 10, 14, 20, 30, 50, 60, 90, 100 and 120 film-coated tablets

Tablet container (HDPE): 30, 60, 90 and 500 film-coated tablets

Not all pack sizes may be marketed

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

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

[To be completed nationally]

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