

Package leaflet: Information for the patient

Perindopril Arginine TAD 5 mg tablets Perindopril Arginine TAD 10 mg 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 TAD is and what it is used for
2. What you need to know before you take Perindopril Arginine TAD
3. How to take Perindopril Arginine TAD
4. Possible side effects
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6. Contents of the pack and other information

1. What Perindopril Arginine TAD is and what it is used for

Perindopril Arginine TAD 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 TAD 5 mg and 10 mg tablets are used:

- to treat high blood pressure (hypertension),
- 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.

Perindopril Arginine TAD 5 mg tablets are also used:

- to treat heart failure (a condition where the heart is unable to pump enough blood to meet the body's needs).

2. What you need to know before you take Perindopril Arginine TAD

Do not take Perindopril Arginine TAD

- 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 TAD 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 TAD 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 for heart failure, 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 TAD”).

Warnings and precautions

Talk to your doctor or pharmacist before taking Perindopril Arginine TAD 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,
- 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 TAD”.

- 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 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),
 - sacubitril (available as fixed-dose combination with valsartan), used to treat long-term heart failure, linagliptin, saxagliptin, sitagliptin, vildagliptin and other drugs belonging to the class of the also 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 TAD. This may occur at any time during treatment. If you develop such symptoms, you should stop taking Perindopril Arginine TAD 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 TAD 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 TAD

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

Treatment with Perindopril Arginine TAD 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 blockers (ARB), aliskiren (see also information under the headings "Do not take Perindopril Arginine TAD" 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 (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 drugs used in the 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 acetylsalicylic acid, a substance presents 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) 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 Arginine TAD" 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),
- 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 TAD with food and drink

It is preferable to take Perindopril Arginine TAD 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 TAD 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 TAD. Perindopril Arginine TAD 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 TAD 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 TAD 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.

3. How to take Perindopril Arginine TAD

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.

Perindopril Arginine TAD 5 mg tablets

The tablet 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 TAD 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 TAD

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 TAD, 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 TAD

As the treatment with Perindopril Arginine TAD 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:

- 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 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)

- 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,
- feeling of weakness.

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,
- 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.

Rare (may affect up to 1 in 1000 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.

Frequency 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 the 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 TAD

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 and blister 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 TAD contains

- The active substance is perindopril arginine.
Perindopril Arginine TAD 5 mg tablets
Each tablet contains 5 mg perindopril arginine, equivalent to 3.395 mg perindopril.
Perindopril Arginine TAD 10 mg tablets
Each tablet contains 10 mg perindopril arginine, equivalent to 6.790 mg of perindopril.
- The other ingredients are calcium chloride hexahydrate, microcrystalline cellulose, colloidal anhydrous silica and magnesium stearate.

What Perindopril Arginine TAD looks like and contents of the pack

Perindopril Arginine TAD 5 mg tablets

White or almost white capsule-shaped tablets, scored on both sides. One side of the tablet is marked with V1 - with V on one side of the score line and 1 on the other side of the score line. Tablet dimensions: approximately 8 mm x 5 mm. The tablet can be divided into equal doses.

Perindopril Arginine TAD 10 mg tablets

White or almost white, round, biconvex tablets marked with V2 on one side of the tablet. Diameter: approximately 8 mm.

Perindopril Arginine TAD is available in boxes containing:

- 10, 30, 60 or 90 tablets in OPA/Alu/PVC//Alu blisters.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

TAD Pharma GmbH, Heinz-Lohmann-Str. 5, 27472 Cuxhaven, Germany

Manufacturer

KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

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

Name of the Member State	Name of the medicinal product
Hungary, Lithuania	Perindopril arginine Krka
Latvia,	Perindopril arginine TAD
Ireland	Perindopril Arginine TAD
Portugal	Perindopril TAD
Croatia, Denmark	Perindoprilarginin Krka
Greece	Perineva
Bulgaria	IPEHECA HEO
Slovenia	NEOPRENESSA
France	PERINDOPRIL ARGININE HCS

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