

PACKAGE LEAFLET: INFORMATION FOR THE USER

AMLESSA

4 mg/5 mg, 4 mg/10 mg, 8 mg/5 mg, 8 mg/10 mg tablets

PERINDOPRIL-TERT-BUTILAMIN/AMLODIPINBESILAT

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 •

What is in this leaflet?

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

1. WHAT AMLESSA IS AND WHAT IT IS USED FOR

Amlessa is prescribed for treatment of high blood pressure (hypertension), and/or for the treatment of stable coronary artery disease (a condition in which the blood supply to the heart is reduced). Patient who are already taking perindopril and amlodipine in the separate tablets can instead take a tablet of Amlessa which contains both of these components.

Amlessa is the combination of the two active components, perindopril and amlodipine. Perindopril is an ACE inhibitor (angiotensin converting enzyme inhibitor). Amlodipine is a calcium antagonist (which belongs to the group of medicines called dihydropyridines). Together, they act in a manner to expand and relax the blood vessels so that the blood passes more easily through them, thereby they lower the blood pressure and ease the maintenance of optimal heart blood flow.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE AMLESSA

Do not use Amlessa

- If you are hypersensitive to perindopril tert-butylamine or any other ACE inhibitor, amlodipine besilate or any dihydropyridine or to any of the other ingredients of Amlessa (see section 6 for the ingredients).
- If you are breast-feeding (see "Pregnancy and lactation")

- If you are pregnant more than 3 months. (It is also better to avoid taking Amlessa in early pregnancy - see pregnancy section).
- If you have had symptoms such as wheezing, swelling of the face or tongue, intense itching or severe skin rashes due to previous ACE inhibitor treatment or if you or another member of the family had similar symptoms in other circumstances (a condition called angioedema).
- If you are in a state of shock (low blood pressure that causes loss of consciousness) including shock caused by heart problems.
- If you have extremely low blood pressure (severe hypotension).
- If you suffer from heart failure (the heart is unable to pump blood adequately, which results in the shallow breathing or swelling of the legs, ankles or feet) after an acute heart attack,
- If you have dynamic narrowing of the heart outflow tract, in which pumping of the blood to the left side of the heart is difficult (eg. At the aortic stenosis)
- If you have diabetes or impaired kidney function and take the drug for lowering blood pressure containing aliskiren.

Take special care with Amlessa

- If you have hypertrophic cardiomyopathy (heart muscle disease) or renal artery stenosis (narrowing of the arteries that bring blood to the kidneys)
- If you have any other heart problems,
- If you have impaired liver function,
- If you have kidney problems or are on dialysis,
- If you have a collagen vascular disease (a disease of the connective tissue) such as systemic lupus erythematosus or scleroderma,
- If you have diabetes,
- If you are on a restricted diet or taking salt substitutes containing potassium salts (a well-balanced potassium levels in the blood is extremely important)
- If you are taking any of the medicines listed below, which are used to treat high blood pressure:
 - An angiotensin II receptor blocker (ARB) (also known as Sartana - eg. Valsartan, telmisartan, irbesartan), especially if you have kidney ailments associated with diabetes.
 - Aliskiren.

Doctor may check kidney function, blood pressure and the amount of electrolytes (eg, potassium) in the blood at regular intervals.

See also information under the heading "Do not take Amlessa" X "

- Be sure to tell your doctor if you suspect that you are pregnant (or might become) pregnant. Intake of Amlessa in early pregnancy is not recommended and must not be taken if you are pregnant more than 3 months since it can cause serious birth defects if used in the above stages of pregnancy (see section on pregnancy).
- If you are taking Amlessa, you also need to inform your doctor or nurse if:
 - Are preparing for a more difficult operation and / or operation that is performed under general anesthesia,
 - Have recently had diarrhea or vomiting (had nausea)
 - Are about to undergo LDL apheresis (removal of cholesterol from the blood using the appliance)
 - Preparing for desensitisation treatment to reduce the effects of an allergy to bee or wasp stings.

Amlessa is not recommended in children and adolescents.

Taking other medicines

- Please tell your doctor, health care provider or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

It is necessary to avoid concomitant use with Amlessa:

- Lithium (used in the treatment of mania, or depression),
- Estramustine (used in cancer treatment)
- Potassium-sparing diuretics (spironolactone, triamterene), potassium supplements, or salt substitutes containing potassium.

Other medications may influence Amlessa treatment. Be sure to tell your doctor if you are taking any of the following medicines as they will be needed additional monitoring:

- Other drugs for the regulation of high blood pressure, including diuretics (drugs that increase the amount of urine produced by the kidneys),
- A non-steroidal anti-inflammatory drugs (eg., Ibuprofen) for pain relief or high dose aspirin,
- Drugs to treat diabetes (such as insulin),
- Drugs to treat mental disorders such as depression, anxiety, schizophrenia and so on. (E.g., tricyclic antidepressants, anti-psychotics, anti-depressants as well as imipramine, neuroleptics),
- Anti-rejection drugs (drugs which reduce the defense mechanism of the body) that are used in the treatment of autoimmune diseases or transplant (e.g., cyclosporine);
- Allopurinol (for the treatment of gout),
- Procainamide (to treat irregular heartbeats)
- Vasodilators including nitrates (products that widen blood vessels)
- Heparin (drugs for diluting the blood),
- Ephedrine, noradrenaline or adrenaline (drugs used to regulate blood pressure, shock or asthma)
- Baclofen or dantrolene (infusion) to be used in the treatment of muscle stiffness in diseases such as multiple sclerosis; dantrolene is also used for the treatment of malignant hyperthermia during anesthesia (symptoms include a high fever and muscle stiffness)
- Some antibiotics, such as rifampicin,
- Antiepileptic drugs such as carbamazepine, phenobarbital, phenytoin, primidone,
- Itraconazole or ketoconazole (medicines used to treat fungal infections)
- Alpha-blocking agents used in the treatment of prostate enlargement, such as prazosin, alfuzosin, doxazosin, tamsulosin, terazosin,
- Amifostine (to be used for the prevention or mitigation of the side effects of other drugs, or radiation therapy for cancer treatment),
- Corticosteroids (used in the treatment of a variety of conditions including severe asthma and rheumatoid arthritis),
- Gold salts, particularly when administered by intravenous (used to treat the symptoms of rheumatoid arthritis).

The doctor may need to change the dose and / or take other precautions:

If you are taking an angiotensin II receptor blocker (ARB) or aliskiren (see also information under the headings "Do not take Amlessa" and "Warnings and precautions"). "

Taking Amlessa with food and drink

Amlessa should be taken before meals.

Simultaneous use of Amlessa with grapefruit juice or grapefruit may lead to increased concentrations of the active substance amlodipine in the blood, which can lead to an increased effect on blood pressure.

Pregnancy and breast-feeding

Ask your doctor, health care provider or pharmacist for advice before taking any medicine.

Inform your doctor if you are planning to become pregnant, or if you are already pregnant.

In most cases, the doctor will advise you to stop taking Amlessa before pregnancy or as soon as you know you are pregnant and will prescribe replacement medicine instead of Amlessa. Taking Amlessa is not recommended in early pregnancy, and must not be taken if you are more than 3 months pregnant since it can cause serious birth defects if used after the third month of pregnancy.

Breastfeeding

Tell your doctor if you are breast-feeding or if you will start to breastfeed. Amlessa is not recommended for mothers who are breast-feeding, and your doctor will most likely choose another drug, if you want to continue breastfeeding, especially if it is a newborn or prematurely born child.

Driving and using machines

Amlessa does not affect the sanity, but occurrence of dizziness or weakness due to reduced blood pressure is possible, which can affect your ability to drive and use machines. It is recommended that you do not operate a vehicle or machinery until you know how you react to Amlessa.

3. HOW TO USE AMLESSA

Always use Amlessa exactly as your doctor or health care provider has told you. You should check with your doctor, health care provider or pharmacist if you are not sure.

Drink a pill with a glass of water, preferably every day at the same time, in the morning before a meal. Your doctor will decide which dose is appropriate for you. Typically this will be one tablet per day. Amlessa is prescribed to patients who are already taking perindopril and amlodipine as separate tablets.

If you use more Amlessa than you should

If you take too many tablets at once, immediately contact the nearest emergency clinic or your doctor. The most likely symptoms of overdose are low blood pressure that makes you feel dizzy or faint. If this happens, it will help if you lie down with your feet up.

If you forget to take Amlessa

It is important to take medicine every day since regular therapy works best. However, if you forget to take prescribed dose Amlessa, take the next dose at the usual time.

Do not take a double dose to make up for a forgotten dose.

If you stop using Amlessa

Since Amlessa treatment usually lasts for a lifetime, you should consult your doctor before you stop taking the tablets.

If you have any further questions on the use of this product, ask your doctor, health care provider or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Side effects may occur at regular intervals, as defined below:

Very common:	Occurring in more than 1 in 10 patients
Common:	Often occur in 1 to 10 in 100 patients
Less common:	Occur in 1 to 10 in 1,000 patients
Rare:	Occur in 1 to 10 in 10,000 patients
Very rare:	Occurring in less than 1 in 10,000 patients
Not known:	Frequency cannot be estimated from the available data

If you experience the following symptoms, stop using the medicine and contact your doctor immediately

- Symptoms of allergic reactions such as swelling of the face, lips, mouth, tongue or throat, difficulty breathing,
- Strong dizziness or fainting,
- Unusually rapid or irregular heartbeat.

Other side effects include:

Common side effects (occurring in less than 1 in 10 patients but more than 1 in 100 patients):

headache, dizziness, vertigo, pins and needles, drowsiness, visual disturbances, tinnitus (noises in the ears), palpitations (a rapid heart rate), facial flushing (hot flashes, or warmth in the face), light-headedness due to low blood pressure, cough, shallow breathing, nausea, vomiting, abdominal pain, taste disturbances, dyspepsia or difficulty with digestion, diarrhea, constipation, allergic reactions (such as rash, itching), muscle cramps, fatigue, edema (swelling of the legs or ankles)

Less common side effects (occurring in less than 1 in 100 patients but more than 1 in 1000 patients):

Mood changes, sleep disorder, tremor, syncope (temporary loss of consciousness), loss of pain sensation, rhinitis (stuffy or runny nose), altered bowel habit, hair loss, red or colorless patches of skin, back pain, muscle pain or joint pain, chest pain, increased urge to urinate especially at night, nausea (feeling of general weakness), bronchospasm (tightness in the chest, rattling and shallow breathing), dry mouth, angioedema (symptoms such as wheezing, swelling of the face or tongue), problems with kidney problems, impotence, sweating, breast enlargement in men, increase or decrease in body weight,

Very rare side effects (occurring in less than 1 in 10 000 patients):

confusion, cardiovascular disorders (irregular heartbeat, angina, heart attack and stroke), eosinophilic pneumonia (a rare type of pneumonia), erythema multiforme (skin rash that often starts the appearance of itchy red spots on the face, hands and feet), blood disorders, pancreas, stomach or liver, peripheral neuropathy (a disease that causes loss of sensation, pain and loss of muscle control), hypertension (abnormally increased muscle tension), vasculitis (inflammation of blood vessels of the skin), swelling of the gums, high blood sugar levels.

If you notice any side effects please tell your doctor or pharmacist.

5. HOW TO STORE AMLESSA

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

Do not store above 30 °C, Store in the original container.

Do not use Amlessa tablets after the expiry date which is stated on the label. The expiry date refers to the last day of that month. Expiry date: 3 years.

6. FURTHER INFORMATION

What Amlessa contains

The active substances are perindopril tert-butylamine, and amlodipine besilate.

Each tablet contains 4 mg of perindopril tert-butylamine and 5 mg of amlodipine in the form of amlodipine besilate.

Each tablet contains 4 mg of perindopril tert-butylamine and 10 mg amlodipine in the form of amlodipine besilate.

Each tablet contains 8 mg of perindopril tert-butylamine and 5 mg of amlodipine in the form of amlodipine besilate.

Each tablet contains 8 mg of perindopril tert-butylamine and 10 mg amlodipine in the form of amlodipine besilate.

The other ingredients are: sodium bicarbonate; microcrystalline cellulose (E460); starch, pregelatinised; sodium starch glycolate type A; silica, colloidal anhydrous and magnesium stearate (E572).

What Amlessa looks like and contents of the pack

4 mg / 5 mg: white to almost white, round, biconvex goods with angled edges.

4 mg / 10 mg: white to off-white, capsule-shaped, biconvex tablets with a dividing notch on one side. Notch is not intended for breaking the tablet.

8mg / 5mg: white to almost white, round, biconvex tablets with beveled edges.

8 mg / 10 mg: white to almost white, round, biconvex tablets with chamfered edges and with a dividing notch on one side.

The tablet can be divided into equal parts.

Amlessa is available in blister, each case contains a total of 30 and 90 tablets.

The regime of dispensing

The medicine is issued on prescription.

Manufacturer

Krka Pharmaceuticals, dd

Šmarješka cesta 6, Novo mesto, Republic of Slovenia

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