

Package leaflet: Information for the patient

Ramipril/Amlodipine Adamed, 2.5 mg/5 mg, capsule, hard
Ramipril/Amlodipine Adamed, 5 mg/5 mg, capsule, hard
Ramipril/Amlodipine Adamed, 5 mg/10 mg, capsule, hard
Ramipril/Amlodipine Adamed, 10 mg/5 mg, capsule, hard
Ramipril/Amlodipine Adamed, 10 mg/10 mg, capsule, hard

Ramipril/Amlodipine

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

1. What Ramipril/Amlodipine Adamed is and what it is used for

Ramipril/Amlodipine Adamed contains two active substances: ramipril and amlodipine. Ramipril belongs to a group of medicines called ACE inhibitors (Angiotensin Converting Enzyme inhibitors). Amlodipine belongs to a group of medicines called calcium antagonists.

Ramipril works by:

- Decreasing your body's production of substances that could raise your blood pressure
- Making your blood vessels relax and widen
- Making it easier for your heart to pump blood around your body

Amlodipine works by:

- Relaxing and widening blood vessels, so that blood passes through them more easily.

Ramipril/Amlodipine Adamed is used to treat hypertension (high blood pressure), in patients whose blood pressure is adequately controlled with amlodipine and ramipril given concurrently at the same dose level as in Ramipril/Amlodipine Adamed, but as a separate medicines.

2. What you need to know before you take Ramipril/Amlodipine Adamed

Do not take Ramipril/Amlodipine Adamed:

- if you are allergic to ramipril, amlodipine (active substances), other ACE inhibitor medicines or any other calcium antagonists, or any of the other ingredients of this medicine (listed in section 6). This may be itching, reddening of the skin or difficulty in breathing.
- If you have ever had a serious allergic reaction called "angioedema". The signs include itching, hives (urticaria), red marks on the hands, feet and throat, swelling of the throat and tongue, swelling around the eyes and lips, difficulty breathing and swallowing.

- 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, as the risk of angioedema (rapid swelling under the skin in an area such as the throat) is increased.
- If you are having dialysis or any other type of blood filtration. Depending on the machine that is used, Ramipril/Amlodipine Adamed may not be suitable for you
- If you have kidney problems where the blood supply to your kidneys is reduced (renal artery stenosis)
- During the last 6 months of pregnancy (see section below on "Pregnancy and breastfeeding")
- If you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren
- If your blood pressure is abnormally low or unstable. Your doctor will need to make this assessment.
- If you have narrowing of the aortic heart valve (aortic stenosis) or cardiogenic shock (a condition where your heart is unable to supply enough blood to the body).
- If you suffer from heart failure after a heart attack.

Do not take Ramipril/Amlodipine Adamed if any of the above apply to you. If you are not sure, talk to your doctor before taking Ramipril/Amlodipine Adamed.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Ramipril/Amlodipine Adamed. Tell your doctor, if any of the situations listed below is applicable to you:

- If you have heart, liver or kidney problems
- If you have recent heart attack
- If you have lost a lot of body salts or fluids (through being sick (vomiting), having diarrhoea, sweating more than usual, being on a low salt diet, taking diuretics (water tablets) for a long time or having had dialysis)
- If you are going to have treatment to reduce your allergy to bee or wasp stings (desensitization)
- If you are going to receive an anesthetic. This may be given for an operation or any dental work. You may need to stop your Ramipril/Amlodipine Adamed treatment one day beforehand; ask your doctor for advice
- If you have high amounts of potassium in your blood (shown in blood test results)
- If you have a collagen vascular disease such as scleroderma or systemic lupus erythematosus
- If you are taking medicines or have conditions which may decrease sodium levels in your blood. Your doctor may carry out regular blood tests, particularly for checking the levels of sodium in your blood especially if you are elderly.
- 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 Ramipril/Amlodipine Adamed".

- You must tell your doctor if you think that you are (or might become) pregnant. Ramipril/Amlodipine Adamed is not recommended in the first 3 months of pregnancy and may cause serious harm to your baby after 3 months of pregnancy (see section below on "Pregnancy and breast-feeding and fertility").
- If you had severe increase in blood pressure (hypertensive crisis)
- If you are elderly and your dose needs to be increased
- If you developed a dry cough which is persistent for a long time
- If your blood pressure is not sufficiently lowered. Medicines of this type seem to be less effective in persons with black skin
- 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 cancer (e.g., temsirolimus, sirolimus, everolimus);
 - Vildagliptin, a medicine used to treat diabetes.
 - Sacubitril/valsartan (see section 2 - "Do not take Ramipril/Amlodipine Adamed")

If you suffer from sudden swelling of the lips and face, tongue and throat, neck, possibly also hands and feet, difficulty to swallow or to breathe, hives or hoarseness ('angioedema'). This could be a sign of a severe allergic reaction. This may occur at any time during the treatment. Persons with black skin may have a higher risk of suffering from this condition. If you develop such symptoms you should let your doctor know immediately.

Children and adolescents

Ramipril/Amlodipine Adamed is not recommended for use in children and adolescents below 18 years of age because there is no information available in this population.

Other medicines and Ramipril/Amlodipine Adamed

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

Tell your doctor if you are taking any of the following medicines. They can make Ramipril/Amlodipine Adamed work less well:

- Medicines used to relieve pain and inflammation (e.g. Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) such as ibuprofen or indomethacin and acetylsalicylic acid).
- Medicines used for the treatment of low blood pressure, shock, cardiac failure, asthma or allergies such as ephedrine, noradrenaline or adrenaline. Your doctor will need to check your blood pressure.
- Rifampicin (antibiotic to treat tuberculosis).
- Hypericum perforatum (St. John's Wort used to treat depression).

Tell your doctor if you are taking any of the following medicines. They can increase the chance of getting side effects if you take them with Ramipril/Amlodipine Adamed:

- Sacubitril/valsartan – used for treating a type of long term (chronic) heart failure in adults (see section 2 'Do not take Ramipril/Amlodipine Adamed')
- Erythromycin, clarithromycin (antibiotics)
- Medicines for cancer (chemotherapy)
- Medicines belonging to the class of mTOR inhibitors; e.g. temsirolimus, everolimus, sirolimus, tacrolimus (used to treat certain types of cancer or to avoid rejection of transplanted organs) See section "Warnings and precautions".
- Tacrolimus (used to control your body's immune response, enabling your body to accept the transplanted organ). See section "Warnings and precautions".
- Ciclosporin, an immunosuppressant medicine used to prevent organ transplant rejection;
- Medicines used to relieve pain and inflammation (e.g. Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) such as ibuprofen or indomethacin and acetylsalicylic acid).
- Diuretics (water tablets) such as furosemide.
- Medicines which can increase the amount of potassium in your blood such as spironolactone, triamterene, amiloride, potassium supplements (including salt substitutes), trimethoprim alone or in combination with sulfamethoxazole for infections caused by bacteria and heparin, a medicine used to thin blood to prevent clots);
- Steroid medicines for inflammation such as prednisolone.
- Allopurinol (used to lower the uric acid in your blood).
- Procainamide (for heart rhythm problems).
- Ketoconazole, itraconazole (anti-fungal medicines).
- Ritonavir, indinavir, nelfinavir (so called protease inhibitors used to treat HIV).
- Verapamil, diltiazem (medicines to treat heart disorders or high blood pressure).
- Dantrolene (infusion for severe body temperature abnormalities).
- Vildagliptin (used for treating type 2 diabetes). See section "Warnings and precautions".
- Racecadotril (used against diarrhoea). See section "Warnings and precautions".

Your doctor may need to change your dose and/or to take other precautions:

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

Please tell your doctor if you are taking any of the following medicines. They may be affected by Ramipril/Amlodipine Adamed:

- Medicines for diabetes such as oral, glucose lowering medicines and insulin. Ramipril/Amlodipine Adamed may lower your blood sugar amounts. Check your blood sugar amounts closely while taking Ramipril/Amlodipine Adamed
- Lithium (for mental health problems). Ramipril/Amlodipine Adamed may increase the amount of lithium in your blood. Your lithium amount will need to be closely checked by your doctor.
- Simvastatin (a cholesterol lowering medicine). Ramipril/Amlodipine Adamed may increase the amount of simvastatin in your blood.

If any of the above apply to you (or you are not sure), talk to your doctor before taking Ramipril/Amlodipine Adamed.

Ramipril/Amlodipine Adamed with food, drink and alcohol

Ramipril/Amlodipine Adamed may be taken with or without food.

Drinking alcohol with Ramipril/Amlodipine Adamed may make you feel dizzy or light-headed. If you are concerned about how much you can drink while you are taking Ramipril/Amlodipine Adamed, discuss this with your doctor as medicines used to reduce blood pressure and alcohol can have additive effects.

Grapefruit juice or grapefruit should not be consumed by people who are taking Ramipril/Amlodipine Adamed. This is because grapefruit and grapefruit juice can lead to an increase in the blood levels of the active ingredient amlodipine, which can cause an unpredictable increase in the blood pressure lowering effect of Ramipril/Amlodipine Adamed.

Pregnancy and 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 should not take Ramipril/Amlodipine Adamed in the first 12 weeks of pregnancy and you must not take it at all from the 13th week as its use during pregnancy may possibly be harmful to the baby.

If you become pregnant while on Ramipril/Amlodipine Adamed, tell your doctor immediately. A switch to a suitable alternative treatment should be carried out in advance of a planned pregnancy.

Breast-feeding

You should not take Ramipril/Amlodipine Adamed if you are breastfeeding.

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

Fertility

There is no sufficient data regarding the potential effect on fertility.

Driving and using machines

Ramipril/Amlodipine Adamed may affect your ability to drive or use machines. If the Ramipril/Amlodipine Adamed make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately. This can happen especially at the start of treatment, or when changing over from other preparations.

Ramipril/Amlodipine Adamed contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

3. How to take Ramipril/Amlodipine Adamed

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

If you have the impression that the effect of Ramipril/Amlodipine Adamed is too strong or too weak, talk to your doctor or pharmacist.

Take this medicine by mouth at the same time of the day, before or after your meal.

Swallow the whole capsule with liquid.

Do not take Ramipril/Amlodipine Adamed with grapefruit juice.
Ramipril/Amlodipine Adamed should be administered once a day.
The doctor may modify the dose, depending on the effect it will have on you.
The maximum daily dose is one capsule 10 mg/10 mg.

Elderly

Your doctor will reduce the initial dose and adjust your treatment more slowly.

Use in children and adolescents

Ramipril/Amlodipine Adamed is not recommended for use in children and adolescents below 18 years of age because there is no information available in this population.

If you take more Ramipril/Amlodipine Adamed than you should

Taking too many capsules may cause your blood pressure to become low or even dangerously low. You may feel dizzy, lightheaded, faint or weak. If blood pressure drop is severe enough shock can occur. Your skin could feel cool and clammy and you could lose consciousness. Tell a doctor or go to the nearest hospital casualty department straight away. Do not drive to the hospital, get somebody else to take you or call for an ambulance. Take the medicine pack with you. This is so the doctor knows what you have taken.

Excess fluid may accumulate in your lungs (pulmonary oedema) causing shortness of breath that may develop up to 24-48 hours after intake.

If you forget to take use Ramipril/Amlodipine Adamed

If you forget to take a capsule, leave out that dose completely. Take your next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

If you stop taking Ramipril/Amlodipine Adamed

Your doctor will advise you how long to take your medicine. Your condition may return if you stop using your medicine before you are advised.

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 Ramipril/Amlodipine Adamed and see a doctor straight away, if you notice any of the following serious side effects – you may need urgent medical treatment:

- Swelling of the face, lips or throat which make it difficult to swallow or breathe, as well as itching and rashes. This could be a sign of a severe allergic reaction to Ramipril/Amlodipine Adamed.
- Severe skin reactions including rash, ulcers in your mouth, worsening of a pre-existing skin disease, reddening, blistering or detachment of skin (such as Stevens-Johnson syndrome, toxic epidermal necrolysis or erythema multiform).

Tell your doctor immediately if you experience:

- Faster heart rate, uneven or forceful heartbeat (palpitations), chest pain, tightness in your chest or more serious problems including heart attack and stroke. The frequencies of these side effects are common (chest pain, tightness in chest, palpitation) or uncommon (faster heart rate, heart attack or stroke).
- Sudden wheeziness, shortness of breath or difficulty in breathing. They are common side effects. These could be signs of lung problems.
- Bruising more easily, bleeding for longer than normal, any sign of bleeding (e.g. bleeding from the gums), purple spots, blotching on the skin or getting infections more easily than usual, sore throat and fever, feeling tired, faint, dizzy or having pale skin. These can be signs of blood or bone marrow problems (the frequency is not known).

- Severe stomach pain which may reach through to your back. This could be a sign of pancreatitis (inflammation of the pancreas). These are uncommon side effects.
- Fever, chills, tiredness, loss of appetite, stomach pain, feeling sick, yellowing of your skin or eyes (jaundice). These can be signs of liver problems such as hepatitis (inflammation of the liver) or liver damage. (the frequency is very rare).

Other side effects include:

Please tell your doctor if any of the following gets serious or lasts longer than a few days.

Very common (may affect more than 1 in 10 people)

- Oedema (fluid retention)

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

- Sleepiness, feeling dizzy (especially at the beginning of treatment)
- Palpitations (awareness of your heart beat), flushing
- Ankle swelling Visual disturbances, double vision,
- Headache or feeling tired, weakness
- Fainting, hypotension (abnormally low blood pressure), especially when you stand or sit up quickly
- Dry tickly cough, inflammation of your sinuses (sinusitis) or bronchitis
- Abdominal pain, stomach or gut pain, diarrhoea, constipation, indigestion, feeling or being sick (vomiting)
- Skin rash with or without raised area
- Chest pain
- Cramps or pain in your muscles
- Blood tests showing more potassium than usual in your blood

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

- Mood changes, sleeplessness
- Trembling, pain, feeling unwell
- Ringing in the ears
- Sneezing/running nose caused by inflammation of the lining of the nose (rhinitis)
- heartburn, dry mouth
- Hair loss, increased sweating, red patches on skin, skin discoloration
- Disorder in passing urine, increased need to urinate, especially at night, increased number of times of passing urine
- Inability to obtain an erection, sexual inability in men, reduced sexual desire in men or women
- Discomfort or enlargement of the breasts in men
- Joint pain, back pain
- Weight increase or decrease
- Balance problems (vertigo)
- Itching and unusual skin sensations such as numbness, tingling, pricking, burning or creeping on your skin (paraesthesia), loss of pain sensation
- Urticaria
- Loss or change in the way things taste
- Feeling depressed, anxious, more nervous than usual or restless
- Blocked nose, difficulty breathing or worsening of asthma
- A swelling in your gut called "intestinal angioedema" presenting with symptoms like abdominal pain, vomiting and diarrhoea
- Loss or decrease of appetite (anorexia)
- blurred vision
- Fever
- An increased number of certain white blood cells (eosinophilia) found during a blood test
- Blood tests showing changes in the way your liver, pancreas or kidneys are working

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

- Feeling shaky or confused
- Red and swollen tongue

- Severe flaking or peeling skin, itchy, lumpy rash
- Nail problems (e.g. loosening or separation of a nail from its bed)
- Skin rash or bruising
- Inflammation of blood vessels, often with skin rash
- Blotches on your skin and cold extremities
- Red, itchy, swollen or watery eyes
- Disturbed hearing
- Blood tests showing a decrease in the number of red blood cells, white blood cells or platelets (which may result in unusual bruising or easy bleeding) or in the amount of haemoglobin

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

- Being more sensitive to the sun than usual
- Excess sugar in blood (hyperglycaemia)
- Swelling of the gums
- Abdominal bloating (gastritis)
- Abnormal liver function, inflammation of the liver (hepatitis), yellowing of the skin (jaundice)
- Increased muscle tension
- Disorders combining rigidity, tremor, and/or movement disorders

Not Known

- 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. If you have these symptoms contact your doctor as soon as possible.
- trembling, rigid posture, mask-like face, slow movements and a shuffling, unbalanced walk.

Other side effects reported:

Please tell your doctor if any of the following gets serious or lasts longer than a few days.

- Difficulty concentrating
- Swollen mouth
- Blood tests showing less sodium than usual in your blood
- Fingers and toes changing colour when you are cold and then tingling or feeling painful when you warm up (Raynaud's phenomenon)
- Slowed or impaired reactions
- Burning sensation
- Change in the way things smell
- Psoriasis.

Reporting of side effects

If you get any side effects, talk to your <doctor> <or> <,> <pharmacist> <or nurse>. 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.

[*For the printed material, please refer to the guidance of the annotated QRD template.]

5. How to store Ramipril/Amlodipine Adamed

Store below 30°C.

Store in the original package in order to protect from light.

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 pack 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 Ramipril/Amlodipine Adamed contains

- The active substances are:
2.5 mg/5 mg, capsule, hard:
each capsule contains 2.5 mg ramipril and amlodipine besilate equivalent to 5 mg amlodipine.
5 mg/5 mg, capsule, hard:
each capsule contains 5 mg ramipril and amlodipine besilate equivalent to 5 mg amlodipine.
5 mg/10 mg, capsule, hard:
each capsule contains 5 mg ramipril and amlodipine besilate equivalent to 10 mg amlodipine.
10 mg/5 mg, capsule, hard:
each capsule contains 10 mg ramipril and amlodipine besilate equivalent to 5 mg amlodipine.
10 mg/10 mg, capsule, hard:
each capsule contains 10 mg ramipril and amlodipine besilate equivalent to 10 mg amlodipine.
- The other ingredients are: cellulose microcrystalline, calcium hydrogen phosphate, anhydrous, maize starch, pregelatinised, sodium starch glycolate (type A), sodium stearyl fumarate, iron oxide red (E 172), titanium dioxide (E 171), gelatine, iron oxide yellow (E 172) (10 mg/10 mg), iron oxide black (E 172) (10 mg/10 mg)

What Ramipril/Amlodipine Adamed looks like and contents of the pack

Ramipril/Amlodipine Adamed 2.5 mg/5 mg, capsule, hard: hard gelatine capsules, approximately 19 mm length, cap: opaque pale pink colour, body: opaque white colour. Content of capsules: white or almost white powder.

Ramipril/Amlodipine Adamed 5 mg/5 mg, capsule, hard: hard gelatine capsules, approximately 19 mm length, cap: opaque pink colour, body: opaque white colour. Content of capsules: white or almost white powder.

Ramipril/Amlodipine Adamed 5 mg/10 mg, capsule, hard: hard gelatine capsules, approximately 19 mm length, cap: opaque red - brown colour, body: opaque white colour. Content of capsules: white or almost white powder.

Ramipril/Amlodipine Adamed 10 mg/5 mg, capsule, hard: hard gelatine capsules, approximately 19 mm length, cap: opaque dark pink colour, body: opaque white colour. Content of capsules: white or almost white powder.

Ramipril/Amlodipine Adamed 10 mg/10 mg, capsule, hard: hard gelatine capsules, approximately 19 mm length, cap: opaque brown colour, body: opaque white colour. Content of capsules: white or almost white powder.

Ramipril/Amlodipine Adamed are available in blister packs containing 28, 30, 32, 56, 60, 90, 91, 96, 98 or 100 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

{To be completed nationally}

Manufacturer

{To be completed nationally}

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

<{Name of the Member State}> <{Name of the medicinal product}>

<{Name of the Member State}> <{Name of the medicinal product}>

This leaflet was last revised 2023-11-17