

Package leaflet: Information for the patient

Rosuvastatin/Amlodipin/Ramipril Adamed 10 mg/5 mg/5 mg, hard capsules
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rosuvastatin/amlodipine/ramipril

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 <Invented name> is and what it is used for
2. What you need to know before you take <Invented name>
3. How to take <Invented name>
4. Possible side effects
5. How to store <Invented name>
6. Contents of the pack and other information

1. What <Invented name> is and what it is used for

<Invented name> contain three active substances called rosuvastatin, amlodipine and ramipril.

- Rosuvastatin belongs to a group of medicines known as statins, which are lipid (fat) regulating medicines. It works by lowering lipids known as cholesterol and triglycerides in the blood.
- Amlodipine belongs to a group of medicines called “calcium channel blockers”. In patients with high blood pressure it works by relaxing blood vessels, so that blood passes through them more easily.
- Ramipril belongs to a group of medicines called “ACE inhibitors (Angiotensin Converting Enzyme Inhibitors)”. In patients with high blood pressure, it works by widening your blood vessels which makes it easier for your heart to pump blood around your body.

<Invented name> is used in adult patients to treat high blood pressure (hypertension) associated with elevated cholesterol levels (primary hypercholesterolaemia) or elevated cholesterol and fat (triglyceride) levels at the same time (combined or mixed hyperlipidaemia) in adult patients.

<Invented name> is intended for patients already on treatment with rosuvastatin, amlodipine and ramipril taken together at the same dose levels as in the combination. With this medicine, you will receive all three active substances, in the same strengths as already take them, but in one capsule.

2. What you need to know before you take <Invented name>

Do not take <Invented name>

- if you are allergic to ramipril or any other ACE inhibitor, to amlodipine or any other calcium channel blocker, to rosuvastatin or any of the other ingredients of this medicine (listed in section 6).
- if your blood pressure is abnormally low or unstable. Your doctor will need to make this assessment.
- if you suffer from heart failure after a heart attack.

- if you have a blockage of the blood flow from the left ventricle of the heart (e.g. high grade aortic stenosis) or shock (including cardiogenic shock, a condition where your heart is unable to supply enough blood to the body).
- if you or a member of your family has 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.
- if you are having dialysis or any other type of blood filtration. Depending on the machine that is used, <Invented name> treatment may not be suitable for you.
- if you have severe kidney problems or kidneys problems where the blood supply to your kidney is reduced (renal artery stenosis).
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.
- have repeated or unexplained muscle aches or pains (myopathy).
- if you have a disease which affects the liver, if you have a liver problem (hepatic impairment) or if you have had any unexplained abnormal blood tests for liver function.
- if you use the combination of sofosbuvir/velpatasvir/voxilaprevir in the treatment of hepatitis C.
- if you use ciclosporin
- if you are pregnant or trying to become pregnant, or if you are a woman able to have children and not using reliable contraception.
- if you are breast-feeding.

Do not take <Invented name> if any of the above apply to you. If you are not sure, talk to your doctor before taking <Invented name>.

Warnings and precautions

Talk to your doctor or pharmacist before taking <Invented name>.

You should inform your doctor if you have or have had any of the following conditions:

- if you have very high blood pressure.
- if you have heart failure (without earlier heart attack, see section 2 *Do not take <Invented name>*) or any other heart problem.
- if you have or have had a recent heart attack.
- if you have less severe kidney problems or kidney disease (see section 2 “*Do not take <Invented name>*”; if in doubt, please ask your doctor).
- you have had repeated or unexplained muscle aches or pains, a personal or family history of muscle problems, or a previous history of muscle problems when taking other cholesterol-lowering medicines. Tell your doctor immediately if you have unexplained muscle aches or pains especially if you feel unwell or have a fever. Also tell your doctor or pharmacist if you have a muscle weakness that is constant.
- 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 to undergo anaesthesia and/or major surgery. An anaesthetic may be given for an operation or any dental work. You may need to stop your <Invented name> treatment one day beforehand; ask your doctor for advice.
- if you have high amounts of potassium in your blood (hyperkalaemia, shown in blood test results) or use salt substitutes which contain potassium.
- 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 have collagen vascular disease such as scleroderma or systemic lupus erythematosus.
- 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.
- if you have severe respiratory failure.
- you are of Asian origin. Your doctor needs to choose the right start dose of [Invented name] to suit you.
- you are over 70 (as your doctor needs to choose the right start dose of [Invented name] to suit you).

- if you are taking or have taken in the last 7 days a medicine called fusidic acid (a medicine for bacterial infection) orally or by injection. The combination of fusidic acid and <Invented name> can lead to serious muscle problems (rhabdomyolysis).
- if you have an under-active thyroid gland (hypothyroidism).
- if you have had repeated or unexplained muscle aches or pains, a personal history or family history of muscle problems.
- if you have had previous muscular problems during treatment with other lipid-lowering medicines (e.g. other ‘-statin’ or ‘-fibrate’ medicines).
- if you regularly drink a large amount (excessive drinking) of alcohol.

If any of the above apply to you, (or you are not sure), talk to your doctor before taking <Invented name>.

Your doctor will need to carry out a blood test before and possibly during your <Invented name> treatment to predict your risk of muscle related side effects. The risk of muscle related side effects e.g. rhabdomyolysis is known to increase when certain medicines are taken at the same time (see section 2 “Other medicines and <Invented name>”).

Take special care with <Invented name>:

Serious skin reactions including Stevens-Johnson syndrome and drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in association with statins treatment. Stop using <Invented name> and seek medical attention immediately if you notice any of the symptoms described in section 4.

While you are on this medicine your doctor will monitor you closely if you have diabetes or are at risk of developing diabetes. You are likely to be at risk of developing diabetes if you have high levels of sugars and fats in your blood, are overweight and have high blood pressure.

In a small number of people, statins can affect the liver. This is identified by a simple test which looks for increased levels of liver enzymes in the blood. For this reason, your doctor will regularly carry out this blood test (liver function test) during treatment with <Invented name>. It is important that you do the prescribed laboratory checks.

Children and adolescents

<Invented name> is not recommended for use in children and adolescents below the age of 18 years.

Other medicines and <Invented name>

Tell your doctor or pharmacist, if you are taking, have recently taken or might take any other medicines. There are some medicines that may change the effect of <Invented name> or their effect may be changed by <Invented name>.

Interaction could make one or both medicines less effective, and it could increase the risk or severity of side-effects, including rhabdomyolysis described in section 4:

- Sacubitril/valsartan – used for treating a type of long term (chronic) heart failure in adults (see section 2 ‘Do not take <Invented name>’).
- other medicines to treat high blood pressure, including aliskiren, angiotensin II receptor blockers (ARBs) also known as sartans (e.g. valsartan, telmisartan, irbesartan), in particular if you have diabetes related kidney problems. See also information under the headings “Do not take <Invented name>”).
- Verapamil, diltiazem (for the treatment of certain heart disease and high blood pressure).
- Medicines to regulate your heart rhythm (procainamide, digoxin).
- Diuretics (water tablets).
- Medicines used for the treatment of low blood pressure, shock, cardiac failure, asthma or allergies such as isoproterenol, dobutamine, dopamine, epinephrine, noradrenaline or adrenaline. Your doctor will need to check your blood pressure.
- Potassium supplements (including salt substitutes), potassium-sparing diuretics (e.g. spironolactone, triamterene, amiloride) and other medicines which can increase the amount of potassium in your blood such as trimethoprim alone or in combination with sulfamethoxazole (for infections caused by bacteria) and heparin (a medicine used to thin blood to prevent clots).

- Medicines used to relieve pain and inflammation (Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) such as ibuprofen or phenazone and acetylsalicylic acid).
- Rifampicin (antibiotic agent used to treat tuberculosis).
- *Hypericum perforatum* (St. John's wort - herbal treatment for depression).
- Medicines for cancer (cytostatics).
- 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).
- Steroid medicines for inflammation such as prednisolone.
- Allopurinol (medicines for the treatment of gout).
- Ketoconazole, itraconazole, voriconazole, fluconazole, posaconazole (used to treat fungal infections).
- Erythromycin, clarithromycin, fusidic acid* (antibiotics used to treat certain bacterial infections).
- Medicines used in the treatment of HIV or liver disease such as Hepatitis C, e.g. ritonavir, lopinavir, atazanavir, indinavir, nelfinavir, darunavir, the combination of tipranavir/ ritonavir, the combination of elbasvir/grazoprevir, ledipasvir/sofosbuvir (so-called protease inhibitors).
- Dantrolene (infusion for severe body temperature abnormalities).
- medicines belonging to the class of so-called mTor inhibitors or Neprilysin (NEP) inhibitors may increase the risk of angioedema as a side effect if used together with <invented name>, e.g.:
 - Temsirolimus (for cancer).
 - Sirolimus, everolimus (for prevention of graft rejection).
 - Vildagliptin (used for treating type 2 diabetes).
 - Racecadotril (to treat diarrhoea). See also section "Warnings and precautions".
- Other medicines to regulate lipid levels, e.g. gemfibrozil, other fibrates, ezetimibe.
- Blood thinners e.g. warfarin or ticagrelor (their blood thinning effect and the risk of bleeding may be increased while taken concomitantly with [invented name]), or clopidogrel;
- An oral contraceptive (the pill). The levels of sexual hormones absorbed from the pill are increased;
- Hormone replacement therapy (increased hormone levels in the blood);
- Darolutamide, Regorafenib (used to treat cancer);
- Fostamatinib (used to treat a low platelet count)
- Febuxostat (used to treat and prevent high levels of uric acid in the blood)
- Teriflunomide (used in the treatment of multiple sclerosis)
- Capmatinib (used to treat cancer),
- Roxadustat (a medicine used to treat symptomatic anemia associated with chronic kidney disease)
- Daptomycin (a medicine used to treat complicated skin and skin structure infections and bacteraemia).
- Tafamidis (a medicine used to treat cardiomyopathy -enlarged and thickened heart muscle)
- Antacids (indigestion products containing aluminium or magnesium).
- Medicines for diabetes such as oral glucose lowering medicines and insulin. <Invented name> may lower your blood sugar amounts. Check your blood sugar amounts closely while taking <Invented name>.
- Simvastatin (medicine to reduce cholesterol): Amlodipine increases the exposure of simvastatin. Your doctor needs to reduce the dose of simvastatin if you take <Invented name>.
- Medicines to treat mental disorders such as depression (tricyclic antidepressants, lithium). <Invented name> may increase the amount of lithium in your blood. Your lithium amount will need to be closely checked by your doctor.
- Baclofen (used to treat muscle stiffness in diseases such as multiple sclerosis)
- Medicines that make the blood vessels become wider (e.g. nitrates, alfuzosin, doxazosin, prazosin, tamsulosin, terazosin)

* If you need to take oral fusidic acid to treat a bacterial infection you will need to temporarily stop using this medicine. Your doctor will tell you when it is safe to restart <Invented name>. Taking <Invented name> with fusidic acid may rarely lead to muscle weakness, tenderness or pain (rhabdomyolysis). See more information regarding rhabdomyolysis in section 4.

If any of the above apply to you (or you are not sure), talk to your doctor before taking <Invented name>.

<Invented name> with food, drink and alcohol

Grapefruit juice and grapefruit should not be consumed by people who are taking <Invented name>. 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 <Invented name>.

Avoid excessive drinking of alcohol while taking this medicine. If you are concerned about how much you can drink, while you are taking <Invented name>, discuss this with your doctor as medicines used to reduce blood pressure and alcohol can intensify each other's sedative effects.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, are trying to get pregnant or think you may be pregnant ask your doctor or pharmacist for advice before taking any medicine.

Pregnancy

Do not take <Invented name> if you are pregnant, if you are trying to become pregnant or if you are able to become pregnant unless you use reliable contraceptive measures(see “Do not take <Invented name>”). This medicine must not be used during pregnancy.

Breast-feeding

You must not take <Invented name> if you are breast-feeding. Tell your doctor immediately if you are breast-feeding or about to start breast-feeding.

Driving and using machines

<Invented name> may affect your ability to drive or use machines. If this medicine makes you feel sick, dizzy or tired, or give you a headache, do not drive or use machines. This is more likely to happen when you start taking this medicine or start taking a higher dose.

<Invented name> contains lactose and sodium

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

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

3. How to take <Invented name>

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

Before you start taking this medicine you should be on a cholesterol-lowering diet. This diet should be continued during treatment with <Invented name>.

This medicine is intended for patients already on treatment with rosuvastatin, amlodipine and ramipril taken together at the same dose levels as in this capsule. Therefore, your doctor will prescribe the capsule corresponding to the strengths of your ongoing treatment.

The recommended dose is 1 capsule per day.

The maximum dose is 1 capsule once daily.

Swallow the capsule whole with a glass of water at the same time each day, with or without food.

<Invented name> and older people (age 65 years or over)

Your doctor should exercise caution during treatment with this medicine, especially if you take the highest dose. Your doctor will frequently monitor your blood pressure while you are taking this medicine.

<Invented name> and patients with renal problems

Your doctor will adjust your dose depending on how your kidneys are working. You must not take this medicine if you have severe kidney failure. Your doctor will monitor your serum potassium concentration and renal function while you are taking this medicine.

<Invented name> and patients with liver problems

You must not take this medicine if you have liver problems.

If you take more <Invented name> than you should

Tell your doctor immediately or contact your nearest accident and emergency department. 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.

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.

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 <Invented name>

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 <Invented name>

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

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 serious side effects or symptoms, stop taking <Invented name> and tell your doctor immediately or go to the nearest hospital accident and emergency department.

- Swelling of the face, lips, mouth, tongue or throat, which makes it difficult to swallow or breathe, as well as itching and rashes. This could be a sign of a severe allergic reaction (angioedema) (frequency uncommon).
- Severe skin reactions including intense skin rash, hives, worsening of a pre-existing skin disease, reddening of the skin over your whole body, severe itching, blistering or detachment of skin, inflammation of mucous membranes (such as Stevens-Johnson syndrome, toxic epidermal necrolysis, Drug reaction with eosinophilia and systemic symptoms (DRESS)) or other allergic reactions (including anaphylactic reaction) (frequency rare).
- Skin rash, which often starts with red itchy patches on your face, arms or legs may form blisters and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge) (exfoliative dermatitis, erythema multiforme) (frequency very rare).
- Muscle weakness, tenderness, pain, rupture or red-brown discolouration of urine and particularly, if at the same time, you feel unwell or have a high temperature it may be caused by an abnormal muscle breakdown (rhabdomyolysis) which can be life-threatening and lead to kidney problems (frequency rare).
- Weakness of arms or legs, or problems speaking which could be a sign of a possible stroke (frequency not known).
- Fast or irregular heartbeat (arrhythmia, including bradycardia, ventricular tachycardia and atrial fibrillation) (frequency common), chest pain, tightness in your chest (angina pectoris, myocardial ischaemia) or heart attack (myocardial infarction) (frequency uncommon).
- 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 failure (frequency not known).
- Severe stomach pain which may reach through to your back. This could be a sign of inflammation of the pancreas (pancreatitis) (frequency uncommon).

Other side effects:

Tell your doctor if you notice any of the following side effects.

Very common: may affect more than 1 in 10 people

- Swelling due to fluid retention (oedema)

Common: may affect up to 1 in 10 people

- Blood potassium increased
- Diabetes. This is more likely if you have high levels of sugars and fats in your blood, are overweight and have high blood pressure. Your doctor will monitor you while you are taking this medicine.
- Headache, dizziness, sleepiness
- Visual disturbances (including double and blurred vision)
- Joint swelling, including ankle swelling
- Low blood pressure (hypotension), especially when you stand or sit up quickly (orthostatic blood pressure decreased), flushing
- Non-productive tickling cough, bronchitis, inflammation of your sinuses (sinusitis), shortness of breath (dyspnoea),
- Abdominal pain, diarrhoea, gastrointestinal inflammation, digestive disturbances and abdominal discomfort, dyspepsia, nausea, altered bowel habits, constipation
- Skin rash with or without raised area
- Muscle spasms, cramps or pain in your muscles (myalgia)
- Feeling exhausted (fatigue)
- Feeling weak and powerless (asthenia)

Uncommon: may affect up to 1 in 100 people

- An increased number of certain white blood cells (eosinophilia) found during a blood test
- Decreased appetite, loss of appetite (anorexia)
- Mood changes, depressed mood, depression, anxiety, nervousness, restlessness, sleep disorders, insomnia, nightmares
- Trembling (tremor), fainting (syncope)
- Unusual skin sensations such as numbness, tingling, pricking, burning or creeping on your skin (paraesthesia), reduced skin sensation (hypoesthesia)
- Loss (ageusia) or change in the way things taste (dysgeusia)
- Ringing in the ears and/ or head (tinnitus)
- Swollen arms and legs (oedema peripheral)
- Sneezing/running nose (rhinitis), blocked nose,
- Difficulties to breath (bronchospasm) including worsening of asthma
- Increase of pancreatic enzymes
- A swelling in your gut called “intestinal angioedema” presenting with symptoms like abdominal pain, vomiting and diarrhoea
- Dry mouth, abdominal pain upper (including gastritis) heartburn, vomiting, eructation
- Blood tests showing changes in the way your liver works (increased hepatic enzymes and/or bilirubin conjugated)
- Sweating more than usual (hyperhidrosis)
- Hair loss (alopecia)
- Itching (pruritus), little bleeding spots or bleeding area in the skin (purpura), skin discolouration, exanthema, urticaria
- pain in your joints (arthralgia)
- back pain
- Kidney problems including acute renal failure, disorders to urinate, passing more urine than usual over the day and/or increased frequency, increased need to urinate at night (nocturia)
- Worsening of pre-existing proteinuria (more proteins than usual in the urine), white blood cells in urine, blood urea increased, blood creatinine increased
- Inability to obtain an erection (impotence), reduced sexual desire in men or women, enlargement of the male breast (gynecomastia)
- Increased body temperature/fever (pyrexia)
- Feeling unwell (malaise)
- Weight increase or decrease

Rare: may affect up 1 in 1 000 people

- Blood tests showing a decrease in the number of red blood cells, white blood cells (including neutropenia or agranulocytosis, leukopenia) or platelets (thrombocytopenia) or in the amount of haemoglobin
- Severe flaking or peeling of the skin, itchy, lumpy rash (exfoliative dermatitis)
- Balance problem
- Confusion
- Red, itchy, swollen or watery eyes (conjunctivitis)
- Impaired hearing
- Narrowing of the blood vessels (vascular stenosis)
- Disturbed blood flow (hypoperfusion)
- Inflammation of the blood vessels (vasculitis)
- Red and swollen tongue (glossitis)
- Yellowing of the skin (jaundice), liver damage
- Nail problems e.g. loosening or separation of a nail from its bed (onycholysis)
- Disturbances or inflammation of the muscles: myopathy (including myositis)
- Lupus-like disease syndrome (including rash, joint disorders and effects on blood cells). Muscle damage

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

- Increases in blood sugar levels (hyperglycaemia; if you have diabetes continue careful monitoring of your blood sugar levels)
- Inflammation of the liver (hepatitis)
- Traces of blood in your urine
- Disorder of the nerves which can cause weakness, tingling or numbness (peripheral neuropathy)
- Damage to the nerves of your legs and arms (such as numbness),
- Increased muscle tension (hypertonia)
- Enlargement of gum tissue (gingival hyperplasia)
- Loss of memory (amnesia)
- Sensitivity to light or sun (photosensitivity)

Not known: frequency cannot be estimated from the available data

- Blood test showing too few red and white blood cells and platelets (pancytopenia)
- Blood tests showing too much damaged red blood cells (haemolytic anaemia)
- Increased antinuclear antibodies
- Acute hepatic failure
- Tendon injury, sometimes complicated by rupture
- 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
- Decrease in blood sodium
- Disturbance in attention
- Impaired psychomotoric skills
- Burning sensation
- Change in the way things smell (parosmia)
- Myasthenia gravis (a disease causing general muscle weakness including in some cases muscles used when breathing)
- Ocular myasthenia (a disease causing eye muscle weakness).
- Trembling, rigid posture, mask-like face, slow movements and a shuffling, unbalanced walk (extrapyramidal disorder)
- Fingers and toes changing colour (getting pale) when you are cold and then tingling or feeling painful when you warm up (Raynaud's phenomenon).
- Inflammation of oral mucosa with small ulcerations (aphtous stomatitis)
- Lumpy skin (pemphigus)
- Inflammation of the skin (dermatitis psoriasiform), acute skin rash (pemphigoid or lichenoid exanthema), worsening of flaking or peeling of the skin (aggravated psoriasis), rash of the mucosa (enanthema)
- Muscle weakness that is constant (immune mediated necrotizing myopathy)

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 <Invented name>

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

Do not store above 30°C. Store in the original package in order to protect from light.

Do not use this medicine after the expiry date which is stated on the carton 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 <Invented name> contains

The active substances are rosuvastatin (as rosuvastatin calcium), amlodipine (as amlodipine besylate) and ramipril.

- <Invented name> 10 mg/5 mg/5 mg hard capsules: each hard capsule contains 10 mg rosuvastatin (as rosuvastatin calcium), 5 mg amlodipine (as amlodipine besylate) and 5 mg ramipril.
- <Invented name> 10 mg/5 mg/10 mg hard capsules: each hard capsule contains 10 mg rosuvastatin (as rosuvastatin calcium), 5 mg amlodipine (as amlodipine besylate) and 10 mg ramipril
- <Invented name> 10 mg/10 mg/10 mg hard capsules: each hard capsule contains 10 mg rosuvastatin (as rosuvastatin calcium), 10 mg amlodipine (as amlodipine besylate) and 10 mg ramipril
- <Invented name> 20 mg/5 mg/5 mg hard capsules: each hard capsule contains 20 mg rosuvastatin (as rosuvastatin calcium), 5 mg amlodipine (as amlodipine besylate) and 5 mg ramipril
- <Invented name> 20 mg/5 mg/10 mg hard capsules: each hard capsule contains 20 mg rosuvastatin (as rosuvastatin calcium), 5 mg amlodipine (as amlodipine besylate) and 10 mg ramipril
- <Invented name> 20 mg/10 mg/10 mg hard capsules: each hard capsule contains 20 mg rosuvastatin (as rosuvastatin calcium), 10 mg amlodipine (as amlodipine besylate) and 10 mg ramipril

Capsule content: lactose monohydrate, croscarmellose sodium, poly(vinyl alcohol), cellulose, microcrystalline, pregelatinised starch, crospovidone, magnesium oxide, heavy, sodium stearyl fumarate

Capsule shell:

10 mg/5 mg/5 mg: gelatine, yellow iron oxide(E172), black iron oxide, brilliant blue FCF – FD&C Blue 1 (E133)

10 mg/5 mg/10 mg: gelatine, red iron oxide(E172), yellow iron oxide(E172)

10 mg/10 mg/10 mg: gelatine, yellow iron oxide(E172), black iron oxide(E172), brilliant blue FCF – FD&C Blue 1 (E133)

20 mg/5 mg/5 mg: gelatine, red iron oxide(E172), yellow iron oxide(E172)

20 mg/5 mg/10 mg: gelatine, red iron oxide(E172), yellow iron oxide(E172), black iron oxide(E172)

20 mg/10 mg/10 mg: gelatine, yellow iron oxide(E172)

Ink: shellac (E904), iron oxide black (E172), propylene glycol, ammonia solution, concentrated, potassium hydroxide

What <Invented name> looks like and contents of the pack

<Invented name> 10mg/5mg/5mg hard capsules, hard gelatin capsule with a length of 22 mm approximately with green cap with black imprint RAR and green body with black imprint 1

<Invented name> 10mg/5mg/10mg hard capsules, hard gelatin capsule with a length of 22 mm approximately with red cap with black imprint RAR and yellow body with black imprint 2

<Invented name> 10mg/10mg/10mg hard capsules, hard gelatin capsule with a length of 22 mm approximately with green cap with black imprint RAR and yellow body with black imprint 3

<Invented name> 20mg/5mg/5mg hard capsules, hard gelatin capsule with a length of 22 mm approximately with red cap with black imprint RAR and red body with black imprint 4

<Invented name> 20mg/5mg/10mg hard capsules, hard gelatin capsule with a length of 22 mm approximately with brown cap with black imprint RAR and yellow body with black imprint 5

<Invented name> 20mg/10mg/10mg hard capsules, hard gelatin capsule with a length of 22 mm approximately with yellow cap with black imprint RAR and yellow body with black imprint 6

Blister made of polyamide-aluminium-PVC (laminate) and aluminium lidding foil: 10, 14, 28, 30, 56, 60, 90, 98 and 100 capsules, in a box.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

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

[To be completed nationally]

This leaflet was last revised in 2026-05-13