

Summary Public Assessment Report

Rosuvastatin/Amlodipin/Ramipril Adamed (rosuvastatin calcium, ramipril, amlodipine besilate)

SE/H/2412/001-006/DC

Summary Public Assessment Report

Rosuvastatin/Amlodipin/Ramipril Adamed

rosuvastatin calcium, rosuvastatin, ramipril, amlodipine, amlodipine besilate

Capsule, hard, 10 mg/5 mg/5 mg, 10 mg/5 mg/10 mg, 10 mg/10 mg/10 mg, 20 mg/5 mg/5 mg, 20 mg/5 mg/10 mg, 20 mg/10 mg/10 mg

This is a summary of the public assessment report (PAR) for Rosuvastatin/Amlodipin/Ramipril Adamed. It explains how the assessment was made and why the authorisation was recommended as well as the conditions of use. It is not intended to provide practical advice on how to use the product.

For practical information about the use of the product, patients should read the package leaflet or contact their doctor or pharmacist.

What is Rosuvastatin/Amlodipin/Ramipril Adamed and what is it used for?

Rosuvastatin/Amlodipin/Ramipril Adamed 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.

Rosuvastatin/Amlodipin/Ramipril Adamed 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.

How does Rosuvastatin/Amlodipin/Ramipril Adamed work?

Rosuvastatin/Amlodipin/Ramipril Adamed 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.
-

How is Rosuvastatin/Amlodipin/Ramipril Adamed used?

The pharmaceutical form is capsule, hard, for oral use.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription in Sweden.

What benefits of Rosuvastatin/Amlodipin/Ramipril Adamed have been shown in studies?

The company provided its own data on efficacy and safety studies. These studies have shown that the product is effective in treating high blood pressure (hypertension) associated with elevated cholesterol levels (primary hypercholesterolaemia).

What are the possible side effects from Rosuvastatin/Amlodipin/Ramipril Adamed?

For the full list of restrictions, see the package leaflet.

Why is Rosuvastatin/Amlodipin/Ramipril Adamed approved?

The Swedish Medical Products Agency decided that the benefits are greater than its risks and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Rosuvastatin/Amlodipin/Ramipril Adamed?

A risk management plan has been developed to ensure that the product is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well. For more details, please see the full PAR for Rosuvastatin/Amlodipin/Ramipril Adamed on the following website: [MRI - Home](#).

Other information about Rosuvastatin/Amlodipin/Ramipril Adamed

The full PAR for Rosuvastatin/Amlodipin/Ramipril Adamed can be found on the following website: [MRI - Home](#). For more information about treatment with Rosuvastatin/Amlodipin/Ramipril Adamed, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2026-07.