Summary Public Assessment Report

Generics

Rosuvastatine Momaja 5 mg, 10 mg, 20 mg and 40 mg film-coated tablets

(rosuvastatin)

NL/H/3366/001-004/DC

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Active substance: rosuvastatin

This is a summary of the public assessment report (PAR) for Rosuvastatine Momaja. It explains how this medicine was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Rosuvastatine Momaja.

For practical information about using this medicine, patients should read the package leaflet or contact their doctor or pharmacist.

What is Rosuvastatine Momaja and what is it used for?
Rosuvastatine Momaja is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Crestor.

This medicine can be used by patients who have a high cholesterol level and are at risk from a heart attack or stroke. Rosuvastatine Momaja belongs to a group of medicines called statins.
It can also be prescribed to patients who have other factors that increase the risk of having a heart attack, stroke or related health problems.

How does this medicine work?
Most of the cholesterol in the blood is made in the liver. Rosuvastatine Momaja reduces cholesterol in the blood in 2 ways:
1. It blocks an enzyme in the liver causing the liver to make less cholesterol;
2. Rosuvastatin increases the uptake and breakdown by the liver of cholesterol already in the blood.

This medicine can reduce the 'bad' cholesterol and increase the 'good' cholesterol. It works by helping to block the body's production of 'bad' cholesterol. It also improves the body's ability to remove it from the blood.

If cholesterol levels are too high, fatty deposits can build up in the walls of the blood vessels causing them to narrow. Sometimes, these narrowed blood vessels can get blocked which can cut off the blood supply to the heart or brain. This may lead to a heart attack or a stroke. By lowering the cholesterol levels, the risk of having a heart attack, a stroke or related health problems is reduced.

How is this medicine used?
The pharmaceutical form of Rosuvastatine Momaja is a film-coated tablet and it is administered orally. The film-coated tablet should be swallowed whole with a drink of water.
The start dose is 5 mg or 10 mg, even if the patient have taken a higher dose of a different statin before. The start dose will depend upon: cholesterol level, level of risk of experiencing a heart attack or stroke and whether the patient is more sensitive to possible side effects. The doctor may decide to increase the dose if necessary. There will be a gap of four weeks between every dose adjustment. The maximum daily dose of Rosuvastatine Momaja is 40 mg. It is only for patients with high cholesterol levels and a high risk of heart attacks or stroke whose cholesterol levels are not lowered enough with 20 mg.

For children and adolescents (aged 10 to 17 years), the usual start dose is 5 mg. The maximum daily dose is 20 mg. The 40 mg tablet should not be used. The medicine can only be obtained with a prescription.

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

How has this medicine been studied?
Because Rosuvastatine Momaja is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Crestor. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects of this medicine?
Because Rosuvastatine Momaja is a generic medicine and is bioequivalent to the reference medicine, its benefits and possible side effects are taken as being the same as the reference medicine.

For the full list of all side effects reported with this medicine, see section 4 of the package leaflet.

Why is this medicine approved?
It was concluded that, in accordance with EU requirements, this medicine has been shown to have comparable quality and to be bioequivalent to the reference medicine. Therefore, the Medicines Evaluation Board of the Netherlands decided that, as for Crestor, the benefits are greater than its risk and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of this medicine?
A risk management plan has been developed to ensure that this medicine 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 for Rosuvastatine Momaja, 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.

Other information about this medicine
In the Netherlands, the marketing authorisation for Rosuvastatine Momaja was granted on 18 April 2016.

The full PAR for this medicine can be found on the website http://mri.medagencies.org/Human. For more information about treatment with Rosuvastatine Momaja, read the package leaflet (http://mri.cts-mrp.eu/Human/Product/Details/46148) or contact your doctor or pharmacist.

This summary was last updated in January 2017.