

Package leaflet: Information for the user

Rosuvastatin Momaja 5 mg film-coated tablets
Rosuvastatin Momaja 10 mg film-coated tablets
Rosuvastatin Momaja 20 mg film-coated tablets
Rosuvastatin Momaja 40 mg film-coated tablets

Rosuvastatin

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 Rosuvastatin Momaja is and what it is used for
- 2) What you need to know before you take Rosuvastatin Momaja
- 3) How to take Rosuvastatin Momaja
- 4) Possible side effects
- 5) How to store Rosuvastatin Momaja
- 6) Contents of the pack and other information

1. What Rosuvastatin Momaja is and what it is used for

Rosuvastatin Momaja belongs to a group of medicines called statins.

You have been prescribed Rosuvastatin Momaja because:

- You have a high cholesterol level. This means you are at risk from a heart attack or stroke. Rosuvastatin Momaja is used in adults, adolescents and children 6 years or older to treat high cholesterol.

You have been advised to take a statin, because changing your diet and taking more exercise were not enough to correct your cholesterol levels. You should continue with your cholesterol-lowering diet and exercise while you are taking Rosuvastatin Momaja.

Or

- You have other factors that increase your risk of having a heart attack, stroke or related health problems.

Heart attack, stroke and other problems can be caused by a disease called atherosclerosis. Atherosclerosis is due to build-up of fatty deposits in your arteries.

Why is it important to keep taking Rosuvastatin Momaja?

Rosuvastatin Momaja is used to correct the levels of fatty substances in the blood called lipids, the most common of which is cholesterol.

There are different types of cholesterol found in the blood – 'bad' cholesterol (LDL-C) and 'good' cholesterol (HDL-C).

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

For most people, high cholesterol does not affect the way they feel because it does not produce any symptoms.

However, if it is left untreated, fatty deposits can build up in the walls of your 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 leading to a heart attack or a stroke. By lowering your cholesterol levels, you can reduce your risk of having a heart attack, a stroke or related health problems.

You need to **keep taking Rosuvastatin Momaja**, even if it has got your cholesterol to the right level, because **it prevents your cholesterol levels from creeping up again** and causing build-up of fatty deposits. However, you should stop if your doctor tells you to do so, or you have become pregnant.

2. What you need to know before you take Rosuvastatin Momaja**Do not take Rosuvastatin Momaja:**

- **If you are allergic to Rosuvastatin** or any of the other ingredients of this medicine (listed in section 6).
- **If you are pregnant** or breast-feeding. If you become pregnant while taking Rosuvastatin Momaja **stop taking it immediately and tell your doctor.** Women should avoid becoming pregnant while taking Rosuvastatin Momaja by using suitable contraception.
- **If you have liver disease.**
- **If you have severe kidney problems.**
- **If you have repeated or unexplained muscle aches or pains.**
- **If you take a medicine called ciclosporin** (used, for example, after organ transplants)

If any of the above applies to you (or you are in doubt), **please go back and see your doctor.**

In addition, do not take Rosuvastatin Momaja 40 mg (the highest dose):

- **If you have moderate kidney problems** (if in doubt, please ask your doctor).
- **If your thyroid gland** is not working properly.
- **If you have had any 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.
- **If you regularly drink large amounts of alcohol.**
- **If you are of Asian origin** (Japanese, Chinese, Filipino, Vietnamese, Korean and Indian).
- **If you take other medicines called fibrates** to lower your cholesterol.

If any of the above applies to you (or you are in doubt), **please go back and see your doctor.**

Warnings and precautions

Talk to your doctor or pharmacist before taking Rosuvastatin Momaja.

- **If you have problems with your kidneys.**
- **If you have problems with your liver.**

- **If 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 regularly drink large amounts of alcohol.**
- **If your thyroid gland** is not working properly.
- **If you take other medicines called fibrates** to lower your cholesterol. Please read this leaflet carefully, even if you have taken other medicines for high cholesterol before.
- **If you take medicines used to treat the HIV infection** for example ritonavir with lopinavir and/or atazanavir, please see **Other medicines and Rosuvastatin Momaja.**
- **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 Rosuvastatin Momaja can lead to serious muscle problems (rhabdomyolysis).

Children and adolescents

- **If the patient is under 6 years old:** Rosuvastatin Momaja should not be given to children younger than 6 years.
- **If the patient is below 18 years of age:** The Rosuvastatin Momaja 40 mg tablets is not suitable for use in children and adolescents below 18 years of age.
- **If you are over 70** (as your doctor needs to choose the right start dose of Rosuvastatin Momaja to suit you)
- **If you have severe respiratory failure.**
- **If you are of Asian origin** – that is Japanese, Chinese, Filipino, Vietnamese, Korean and Indian. Your doctor needs to choose the right start dose of Rosuvastatin Momaja to suit you.

If any of the above applies to you (or if you are not sure):

- **Do not take Rosuvastatin Momaja 40 mg (the highest dose) and check with your doctor or pharmacist before you actually start taking any dose of Rosuvastatin Momaja.**

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 usually carry out this blood test (liver function test) before and during treatment with Rosuvastatin Momaja.

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.

Other medicines and Rosuvastatin Momaja

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: ciclosporin (used for example, after organ transplants), warfarin (or any other medicines used for thinning the blood), fibrates (such as gemfibrozil, fenofibrate) or any other medicine used to lower cholesterol (such as ezetimibe), indigestion remedies (used to neutralise acid in your stomach), erythromycin (an antibiotic), an oral contraceptive (the pill), hormone replacement therapy or anti-viral medicines such as ritonavir with lopinavir and/or atazanavir or simeprevir (used to treat infections, including the HIV or hepatitis C infection – please see Warnings and precautions). The effects of these medicines could be changed by Rosuvastatin Momaja or they could change the effects of Rosuvastatin Momaja.

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 Rosuvastatin Momaja. Taking Rosuvastatin Momaja with fusidic acid may rarely lead to muscle weakness, tenderness or pain (rhabdomyolysis). See more information regarding rhabdomyolysis in section 4.

Pregnancy and breast-feeding

Do not take Rosuvastatin Momaja if you are pregnant or breast-feeding. If you become pregnant while taking Rosuvastatin Momaja **stop taking it immediately** and tell your doctor. Women should avoid becoming pregnant while taking Rosuvastatin Momaja by using suitable contraception.

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.

Driving and using machines

Most people can drive a car and operate machinery while using Rosuvastatin Momaja – it will not affect their ability. However, some people feel dizzy during treatment with Rosuvastatin Momaja. If you feel dizzy, consult your doctor before attempting to drive or use machines.

Rosuvastatin Momaja contains lactose.

If you have been told by your doctor that you have an intolerance to some sugars (lactose or milk sugar), contact your doctor before taking Rosuvastatin Momaja.

For a full list of ingredients, please see Section 6, **'Contents of the pack and other information.'**

3. How to take Rosuvastatin Momaja

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

Usual doses in adults**If you are taking Rosuvastatin Momaja for high cholesterol:****Starting dose**

Your treatment with Rosuvastatin Momaja must start with the **5 mg or the 10 mg dose**, even if you have taken a higher dose of a different statin before. The choice of your start dose will depend upon:

- Your cholesterol level.
- The level of risk you have of experiencing a heart attack or stroke.
- Whether you have a factor that may make you more sensitive to possible side effects.

Please check with your doctor or pharmacist which start dose of Rosuvastatin Momaja will best suit you. Your doctor may decide to give you the lowest dose (5 mg) if:

- You are of **Asian origin** (Japanese, Chinese, Filipino, Vietnamese, Korean and Indian).
- You are **over 70 years** of age.
- You have moderate kidney problems.
- You are at risk of muscle aches and pains (myopathy).

5 mm

Increasing the dose and maximum daily dose

Your doctor may decide to increase your dose. This is so that you are taking the amount of Rosuvastatin Momaja that is right for you. If you started with a 5 mg dose, your doctor may decide to double this to 10 mg, then 20 mg and then 40 mg if necessary. If you started on 10 mg, your doctor may decide to double this to 20 mg and then 40 mg if necessary. There will be a gap of four weeks between every dose adjustment.

The maximum daily dose of Rosuvastatin 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.

If you are taking Rosuvastatin Momaja to reduce your risk of having a heart attack, stroke or related health problems:

The recommended dose is 20 mg daily. However, your doctor may decide to use a lower dose if you have any of the factors mentioned above.

Use in children and adolescents aged 6-17 years

The usual start dose is 5 mg. Your doctor may increase your dose to find the right amount of Rosuvastatin Momaja for you. The maximum daily dose of Rosuvastatin Momaja is 10 mg for children aged 6 to 9 years and 20 mg for children aged 10 to 17 years. Take your dose once a day. Rosuvastatin Momaja 40 mg tablet should not be used by children.

Taking your tablets

Swallow each tablet whole with a drink of water.

Take Rosuvastatin Momaja once daily. You can take it at any time of the day with or without food.

Try to take your tablet at the same time every day to help you to remember it.

Regular cholesterol checks

It is important to go back to your doctor for regular cholesterol checks, to make sure your cholesterol has reached and is staying at the correct level.

Your doctor may decide to increase your dose so that you are taking the amount of Rosuvastatin Momaja that is right for you.

If you take more Rosuvastatin Momaja than you should Contact your doctor or nearest hospital for advice.

If you go into hospital or receive treatment for another condition, tell the medical staff that you're taking Rosuvastatin Momaja.

If you forget to take Rosuvastatin Momaja

Don't worry, just take your next scheduled dose at the correct time. Do not take a double dose to make up for a forgotten dose.

If you stop taking Rosuvastatin Momaja

Talk to your doctor if you want to stop taking Rosuvastatin Momaja. Your cholesterol levels might increase again if you stop taking Rosuvastatin Momaja.

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.

It is important that you are aware of what these side effects may be. They are usually mild and disappear after a short time.

Stop taking Rosuvastatin Momaja and seek medical help immediately if you have any of the following allergic reactions:

- Difficulty in breathing, with or without swelling of the face, lips, tongue and/or throat
- Swelling of the face, lips, tongue and/or throat, which may cause difficulty in swallowing
- Severe itching of the skin (with raised lumps).

Also, stop taking Rosuvastatin Momaja and talk to your doctor immediately if you have any unusual aches or pains in your muscles which go on for longer than you might expect. Muscle symptoms are more common in children and adolescents than in adults. As with other statins, a very small number of people have experienced unpleasant muscle effects and rarely these have gone on to become a potentially life threatening muscle damage known as *rhabdomyolysis*.

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

- Headache
- Stomach pain
- Constipation
- Feeling sick
- Muscle pain
- Feeling weak
- Dizziness
- An increase in the amount of protein in the urine - this usually returns to normal on its own without having to stop taking your Rosuvastatin Momaja tablets (only Rosuvastatin Momaja 40 mg)
- 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.

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

- Rash, itching or other skin reactions
- An increase in the amount of protein in the urine - this usually returns to normal on its own without having to stop taking your Rosuvastatin Momaja tablets (only Rosuvastatin Momaja 5 mg, 10 mg and 20 mg).

Rare possible side effects (may affect up to 1 in 1,000 people):

- Severe allergic reaction – signs include swelling of the face, lips, tongue and/or throat, difficulty in swallowing and breathing, a severe itching of the skin (with raised lumps). **If you think you are having an allergic reaction, then stop taking Rosuvastatin Momaja and seek medical help immediately**
- Muscle damage in adults – as a precaution, **stop taking Rosuvastatin Momaja and talk to your doctor immediately if you have any unusual aches or pains** in your muscles which go on for longer than expected
- A severe stomach pain (inflamed pancreas)
- Increase in liver enzymes in the blood

Very rare possible side effects (may affect up to 1 in 10,000 people):

- Jaundice (yellowing of the skin and eyes)
- Hepatitis (an inflamed liver)
- Traces of blood in your urine
- Damage to the nerves of your legs and arms (such as numbness)
- Joint pain
- Memory loss
- Breast enlargement in men (gynaecomastia)

Side effects of not known frequency (frequency cannot be estimated from the available data):

- Diarrhoea (loose stools)
- Stevens-Johnson syndrome (serious blistering condition of the skin, mouth, eyes and genitals)
- Cough
- Shortness of breath
- Oedema (swelling)
- Sleep disturbances, including insomnia and nightmares
- Sexual difficulties
- Depression
- Breathing problems, including persistent cough and/or shortness of breath or fever
- Tendon injury
- Muscle weakness that is constant

Reporting of side effects:

If you get any side effects talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet. You can also report side effects directly via the details below. By reporting side effects you can help provide more information on the safety of this medicine.

HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@hpra.ie

5. How to store Rosuvastatin Momaja

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 box/blisters/label after EXP. The expiry date refers to the last day of that month.

For OPA/Al/PVC-Al blisters: Do not store above 30°C.
For HDPE bottles: This medicinal product does not require any special storage conditions.

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 Rosuvastatin Momaja contains:**

- The active substance is rosuvastatin.
Rosuvastatin Momaja film-coated tablets contain rosuvastatin calcium equivalent to 5 mg, 10 mg, 20 mg or 40 mg of rosuvastatin.

- The other ingredients are:

Tablet core: calcium hydrogen phosphate dihydrate, cellulose, microcrystalline (Type 102) (E460), lactose monohydrate, crospovidone (Type A) (E1202), magnesium stearate (E572),

Tablet coat: lactose monohydrate, hypromellose (E464), titanium dioxide (E171), triacetin (E1518), iron oxide yellow (E172), iron oxide red (E172).

What Rosuvastatin Momaja looks like and contents of the pack

Rosuvastatin Momaja comes in following pack sizes.
Blisters:

For 5 mg, 10 mg and 20 mg: OPA/Al/PVC-Al blisters in pack-sizes of 14 or 28 film-coated tablets
For 40 mg: OPA/Al/PVC-Al blisters in pack-sizes of 7, 14 or 28 film-coated tablets

Bottles:

For 5 mg, 10 mg, 20 mg and 40 mg: White opaque HDPE container having white opaque PP closure containing a silica gel desiccant in pack size of 30 or 90 film-coated tablets.

Not all pack sizes may be marketed.

Rosuvastatin Momaja comes in four tablet strengths:

Rosuvastatin Momaja 5 mg film-coated tablets are yellow, round, biconvex, coated tablets of approximately 7.1 mm in diameter, debossed with '5' on one side and 'B' on other side.

Rosuvastatin Momaja 10 mg film-coated tablets are pink, round, biconvex, coated tablets of approximately 7.1 mm in diameter, debossed with '10' on one side and 'B' on other side.

Rosuvastatin Momaja 20 mg film-coated tablets are pink, round, biconvex, coated tablets of approximately 9.1 mm in diameter, debossed with '20' on one side and 'B' on other side.

Rosuvastatin Momaja 40 mg film-coated tablets are pink, oval, biconvex, coated tablets of approximately 11.6 mm in length and 7.1 mm in width, debossed with '40' on one side and 'B' on other side.

Marketing Authorisation Holder

Momaja s.r.o.,
Karolinska 650/1, Karlin,
18600, Prague 8,
Czech Republic

Manufacturer

Wave Pharma Limited,
4th Floor, Cavendish House,
369 Burnt Oak Broadway,
Edgware HA8 5AW,
United Kingdom

This medicinal product is authorised in the Member States of the EEA under the following name(s):

- BG : Росувастатин Момая 5 mg, 10 mg, 20 mg, 40 mg филмирани таблетки
- CZ : Rosuvastatin Momaja 5 mg, 10 mg, 20 mg, 40 mg potahované tablety
- EE : Rosuvastatin Momaja
- FI : Rosuvastatin Momaja 5 mg, 10 mg, 20 mg, 40 mg tabletti, kalvopäällysteinen
- HU : Rosuvastatin Momaja 5 mg, 10 mg, 20 mg, 40 mg filmtabletta
- IE : Rosuvastatin Momaja 5 mg, 10 mg, 20 mg, 40 mg film-coated tablets
- NL : Rosuvastatine Momaja 5 mg, 10 mg, 20 mg, 40 mg filmomhulde tabletten
- NO : Rosuvastatin Momaja
- PL : Rosuvastatin Momaja
- RO : Rosuvastatină Momaja 5 mg, 10 mg, 20 mg, 40 mg comprimate filmate

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PET00XXX-XX
XX/XX/0000/00

ARTWORK DETAILS

190 MM

Biocon Limited - Rosuvastatin EU; NP-Ireland		ACTUAL SIZE	Size : 190 (W) x 590 (H) mm
PRODUCT	Rosuvastatin-EU-5-10-20-40-Momaja-PI-Single Language	DESIGN / STYLE	-
PACK	-	SPECIFICATIONS	Common-EN
COMPONENT	Leaflet	PANTONE COLOURS	■ Black
ARTWORK CODE	XX/XX/0000/00	FONTS	Times New Roman
ARTWORK ISSUE	05-02-2016	MINIMUM FONT SIZE	10 pt.
SPECIAL INSTRUCTIONS (IF ANY)		P. Green C color to be referred for DIE key line	
Created by	Reviewed by	Approved by	

\\Bilcom2711d\ARTWORKS\SDK MURTHY\GENERAL EXPORTS\ANDAI\Rosuvastatin EU-NP-Ireland\Momaja-Single Language\Rosuvastatin-EU-5-10-20-40-Momaja-PI-Single Language

8 mm



590 mm

