

ROSUVASTATIN 5 mg, 10 mg, 20 mg, 40 mg Film-coated tablet		
1.3.1 SmPC, Labelling and Package Leaflet	DSM SINOCHEM PHARMACEUTICALS NETHERLANDS B.V	Version no. 1.4

PACKAGE LEAFLET: INFORMATION FOR THE USER

Rosuvastatin <NAME> 5 mg film-coated tablets
Rosuvastatin <NAME> 10 mg film-coated tablets
Rosuvastatin <NAME> 20 mg film-coated tablets
Rosuvastatin <NAME> 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 or nurse.
- **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 or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Rosuvastatin <NAME> is and what it is used for

Rosuvastatin <NAME> belongs to a group of medicines called statins.

You have been prescribed Rosuvastatin <NAME> because:

- You have a high cholesterol level. This means you are at risk from a heart attack or stroke. Rosuvastatin <NAME> 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 <NAME>.

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.

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Why it is important to keep taking Rosuvastatin <NAME>

Rosuvastatin <NAME> 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 <NAME> 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 <NAME>, 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 <NAME>

Do not take Rosuvastatin <NAME>:

- **If you have ever had an allergic reaction to Rosuvastatin <NAME>**, or to any of its ingredients.
 - **If you are pregnant or breast-feeding.** If you become pregnant while taking Rosuvastatin <NAME> stop taking it immediately and tell your doctor. Women should avoid becoming pregnant while taking Rosuvastatin DSM Sinochem 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 drug 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 <NAME> 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.**

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Warnings and precautions

Talk to your doctor or pharmacist before taking Rosuvastatin <NAME>:

- **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 fight the HIV infection** e.g. ritonavir with lopinavir and /or atazanavir, please see “**Other medicines and Rosuvastatin <NAME>**”
- **If you take antibiotics containing fusidic acid**, please see **Other medicines and Rosuvastatin <NAME>**

Children and adolescents

- **If the patient is under 6 years old:** Rosuvastatin <NAME> should not be given to children younger than 6 years.
- **If the patient is below 18 years of age:** The Rosuvastatin <NAME> 40 mg tablet 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 <NAME> 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 <NAME> to suit you.

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

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

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 <NAME>.

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 <NAME>

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:

- cyclosporine (used for example, after organ transplants),
- warfarin or clopidogrel (or any other drug used for thinning the blood),

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- 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), fusidic acid (an antibiotic – please see Warnings and precautions),
 - an oral contraceptive (the pill),
 - hormone replacement therapy,
 - anti-viral medications such as ritonavir with lopinavir and/or atazanavir or simeprevir (used to treat infections, including HIV or hepatitis C infection – please see Warnings and precautions)
- The effects of these medicines could be changed by Rosuvastatin <NAME> or they could change the effects of Rosuvastatin <NAME>.

Rosuvastatin <NAME> with food and drink

You can take Rosuvastatin DSM Sinochem with or without food.

Pregnancy and breast-feeding

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

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

Driving and using machines

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

Rosuvastatin <NAME> contains lactose monohydrate.

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 <NAME>.

Rosuvastatin <NAME> 5 mg, 10 mg and 20 mg contain **sunset yellow FCF (E110)** which may cause allergic reactions.

Rosuvastatin <NAME> 10 mg and 20 mg contain **Allura Red AC Aluminium Lake (E129)** which may cause allergic reactions.

3. How to take Rosuvastatin <NAME>

Always take this medicine exactly 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 <NAME> for high cholesterol:

Starting dose:

Your treatment with Rosuvastatin <NAME> 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.

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Please check with your doctor or pharmacist which start dose of Rosuvastatin <NAME> 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).

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 <NAME> 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 <NAME> 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 <NAME> 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 <NAME> for you. The maximum daily dose of Rosuvastatin <NAME> 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 <NAME> 40 mg tablet should not be used by children.

Taking your tablets

Swallow each tablet whole with a drink of water.

Take Rosuvastatin <NAME> once daily. You can take it at any time of the day. Try to take your tablet at the same time every day to help you to remember it.

The tablets can be taken with or without food.

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 <NAME> that is right for you.

If you take more Rosuvastatin <NAME> than you should

Contact your doctor or nearest hospital for advice.

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

If you forget to take Rosuvastatin <NAME>

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 <NAME>

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

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 <NAME> 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 <NAME> 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 **between 1 in 10 people and 1 in 100 patients**):

- 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 DSM Sinochem tablets (only Rosuvastatin DSM Sinochem 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 <NAME> tablets (only Rosuvastatin <NAME> 5 mg, 10 mg and 20 mg).

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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 <NAME> and seek medical help immediately
- Muscle damage in adults – as a precaution, **stop taking Rosuvastatin <NAME> 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 unknown frequency (frequency cannot be estimated from the available data) **may include:**

- 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, 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.

5. How to store Rosuvastatin <NAME>

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 after EXP. The expiry date refers to the last day of that month.

Store below 25°C. Store in the original blister packaging in order to protect from light and moisture.

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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 <NAME> contains:

Rosuvastatin <NAME> 5 mg film-coated tablets

- The active substance is rosuvastatin. Each film-coated tablet contains rosuvastatin calcium equivalent to 5 mg of rosuvastatin.
- *The other ingredients are: **core*** - lactose monohydrate, microcrystalline cellulose, calcium carbonate, crospovidone type A, magnesium stearate; ***coating*** - Opadry II® Yellow 85F220102 (polyvinyl alcohol partially hydrolysed (E1203), titanium dioxide (E 171), Macrogol/PEG 4000 (E1521), talc (E553b), quinoline yellow (E104), Sunset Yellow FCF (E110)).

Rosuvastatin <NAME> 10 mg film-coated tablets

- The active substance is rosuvastatin. Each film-coated tablet contains rosuvastatin calcium equivalent to 10 mg of rosuvastatin.
- *The other ingredients are: **core*** - lactose monohydrate, microcrystalline cellulose, calcium carbonate, crospovidone type A, magnesium stearate; ***coating*** - Opadry II® Pink 85F240097 (polyvinyl alcohol partially hydrolysed) (E1203), titanium dioxide (E171), macrogol/PEG 4000 (E1521), talc (E553b), Sunset Yellow FCF (E110), Allura Red AC (E 129), Indigo Carmine (E 132)).

Rosuvastatin <NAME> 20 mg film-coated tablets

- Active substance is rosuvastatin. Each film-coated tablet contains rosuvastatin calcium equivalent to 20 mg of rosuvastatin.
- *The other ingredients are: **core*** - lactose monohydrate, microcrystalline cellulose, calcium carbonate, crospovidone type A, magnesium stearate; ***coating*** - Opadry II® Pink 85F240097 (polyvinyl alcohol partially hydrolysed, titanium dioxide (E 171), macrogol/PEG 4000 (E1521), talc (E553b), Sunset Yellow FCF (E110), Allura Red AC (E 129), Indigo Carmine (E 132)).

Rosuvastatin <NAME> 40 mg film-coated tablets

- Active substance is rosuvastatin. Each film-coated tablet contains rosuvastatin calcium equivalent to 40 mg of rosuvastatin.
- *The other ingredients are: **core*** - lactose monohydrate, microcrystalline cellulose, calcium carbonate, crospovidone type A, magnesium stearate; ***coating*** - Opadry II® White II 85F28751 (polyvinyl alcohol partially hydrolysed) E1203, titanium dioxide (E 171), macrogol/PEG 4000 ((E1521), talc(E553b)

What Rosuvastatin <NAME> looks like and contents of the pack

Rosuvastatin <NAME> 5 mg film-coated tablets

Yellow, round, biconvex, film-coated tablets and 7.0 mm±0.5 mm in diameter
OPA–Al–PVC/Al blisters of 7, 14, 15, 20, 28, 28, 30, 42, 50, 56, 60, 84, 90, 98 and 100 film-coated tablets.

Rosuvastatin <NAME> 10 mg film-coated tablets

Pink, round, biconvex, film-coated tablets, embossed ‘R’ on one side and ‘10’ on the other side and 7.0 mm±0.5 mm in diameter

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OPA–Al–PVC/Al blisters of 7, 14, 15, 20, 28, 30, 42, 50, 56, 60, 84, 90, 98 and 100 film-coated tablets.

Rosuvastatin <NAME> 20 mg film-coated tablets

Pink, round, biconvex, film-coated tablets, embossed ‘R’ on one side and ‘20’ on the other side and 9.0 mm±0.5 mm in diameter.

OPA–Al–PVC/Al blisters of 7, 14, 15, 20, 28, 30, 42, 50, 56, 60, 84, 90, 98 and 100 film-coated tablets.

Rosuvastatin <NAME> 40 mg film-coated tablets

White, round, biconvex, film-coated tablets and 9.0 mm±0.5 mm in diameter.

OPA–Al–PVC/Al blisters of 7, 14, 15, 20, 28, 30, 42, 50, 56, 60, 84, 90, 98 and 100 film-coated tablets.

<Not all pack sizes may be marketed>

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

[to be completed Nationally]

Manufacturer

Antibiotice S.A.
1 Valea Lupului Street
707410 Iasi
Romania

This product is authorised in the Member States of the European Economic Area under the following name:

Nederland	Rosuvastatine DSM Sinochem 5 mg, 10 mg 20 mg en 40 mg filmomhulde tabletten
United Kingdom	Rosuvastatin DSM Sinochem 5 mg, 10 mg, 20 mg and 40 mg film-coated tablets
Ireland	Rosuvastatin DSM Sinochem 5 mg, 10 mg, 20 mg and 40 mg film-coated tablets

This leaflet was last revised in: