BROWN & BURK UK LTD
MODULE 1 ADMINISTRATIVE AND PRESCRIBING INFORMATION
MODULE 1.3 PRODUCT INFORMATION
Rosuvastatin 5 mg, 10 mg, 20 mg & 40 mg Film-Coated Tablets.

MODULE 1: ADMINISTRATIVE AND PRESCRIBING INFORMATION

MODULE 1.3 PRESCRIBING INFORMATION

MODULE 1.3.1 PACKAGE LEAFLET

PACKAGE LEAFLET

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Rosuvastatin 5 mg, 10 mg, 20 mg & 40 mg Film-Coated Tablets.

Package Leaflet: Information for the patient

Rosuvastatin 5 mg film-coated tablets
Rosuvastatin 10 mg film-coated tablets
Rosuvastatin 20 mg film-coated tablets
Rosuvastatin 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 tablets is and what it is used for
2. What you need to know before you take Rosuvastatin tablets
3. How to take Rosuvastatin tablets
4. Possible side effects
5. How to store Rosuvastatin tablets
6. Contents of the pack and other information

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

Rosuvastatin tablets belongs to a group of medicines called statins.

You have been prescribed Rosuvastatin tablets because:
- You have a high cholesterol level. This means you are at risk from a heart attack or stroke. Rosuvastatin tablets 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 doing 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 tablets.

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 it is important to keep taking Rosuvastatin tablets?

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Rosuvastatin tablets 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 tablets 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 tablets,** 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 tablets

Do not take Rosuvastatin tablets:

- **If you have ever had an allergic reaction 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 tablets **stop taking it immediately and tell your doctor**. Women should avoid becoming pregnant while taking Rosuvastatin tablets 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 combination of sofosbuvir/velpatasvir/voxilaprevir** (used for viral infection of the liver called hepatitis C).
- **If you take a drug called ciclosporin** (used, for example, after organ transplants)
- If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking Rosuvastatin.

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 tablets 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 tablets.

- **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** e.g. ritonavir with lopinavir and/or atazanavir, please see "**Other medicines and Rosuvastatin tablets".**
- **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 tablets can lead to serious muscle problems (rhabdomyolysis), please see "**Other medicines and Rosuvastatin tablets".**
- **If you are over 70** (as your doctor needs to choose the right start dose of Rosuvastatin tablets 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 tablets to suit you.
- Serious skin reactions including Stevens-Johnson syndrome and drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in association with Rosuvastatin treatment. Stop using Rosuvastatin and seek medical attention immediately if you notice any of the symptoms described in section 4.
- If you have or have had myasthenia (a disease with general muscle weakness including in some cases muscles used when breathing), or ocular myasthenia (a disease causing eye muscle weakness) as statins may sometimes aggravate the condition or lead to the occurrence of myasthenia (see section 4).

If any of the above applies to you (or if you are not sure):
Do not take Rosuvastatin tablets 40 mg (the highest dose) and check with your doctor or pharmacist before you actually start taking any dose of Rosuvastatin tablets.

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 tablets.

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.

Children and adolescents

- **If the patient is under 6 years old**: Rosuvastatin tablets should not be given to children younger than 6 years.

- **If the patient is below 18 years of age**: The Rosuvastatin tablets 40 mg is not suitable for use in children and adolescents below 18 years of age.

Other medicines and Rosuvastatin tablets

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),
- belumosudil (used to treat chronic graft-versus-host disease),
- warfarin or clopidogrel or ticagrelor (or any other drug 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 neutralize acid in your stomach),
- erythromycin (an antibiotic), fusidic acid (an antibiotic – please see below and Warnings and precautions)
- an oral contraceptive (the pill),
- regorafenib (used to treat cancer),
- darolutamide (used to treat cancer),
- capmatinib (used to treat cancer),
- momelotinib (used to treat myelofibrosis, a rare form of blood cancer),
- hormone replacement therapy
- fostamatinib (used to treat low platelet counts),
- febuxostat (used to treat and prevent high blood levels of uric acid),
- teriflunomide (used to treat multiple sclerosis),
- any of the following drugs used to treat viral infections, including HIV or hepatitis C infection, alone or in combination (please see Warnings and precautions): ritonavir, lopinavir, atazanavir, sofosbuvir, voxilaprevir, ombitasvir, paritaprevir, dasabuvir, velpatasvir, grazoprevir, elbasvir, glecaprevir, pibrentasvir.
- Roxadustat or vadadustat (medicines that increase the number of red blood cells and haemoglobin level in chronic kidney disease patients),
- enasidenib (used to treat acute myeloid leukemia),
- tafamidis (used to treat transthyretin amyloidosis),
- Eltrombopag (medication used to regulate low blood platelet counts)
- Dronedarone (medication used to regulate the heart beat)
- Itraconazole (antifungal medicine used to treat fungal infection)

The effects of these medicines could be changed by Rosuvastatin tablets or they could change the effects of Rosuvastatin tablets.

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 tablets. Taking Rosuvastatin tablets 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

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 tablets – it will not affect their ability. However, some people feel dizzy during treatment with Rosuvastatin tablets. If you feel dizzy, consult your doctor before attempting to drive or use machines.

Rosuvastatin tablets contains lactose

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

Rosuvastatin tablets contains sodium

This medicine contains less than 1mmol sodium (23 mg) per tablet, that is to say essentially 'sodium free'.

Rosuvastatin tablets contain the following colours: Allura red AC (E129), Tartrazine (E102) or Sunset Yellow FCF (E110). These may cause allergic reactions.

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

3. How to take Rosuvastatin tablets

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

Usual doses in adults

If you are taking Rosuvastatin tablets for high cholesterol:

Starting dose

Your treatment with Rosuvastatin tablets 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 tablets 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 tablets 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 tablets 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 tablets 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 dose range in children and adolescents aged 6 to 17 years is 5 to 20 mg once daily. The usual start dose is 5 mg per day, and your doctor may gradually increase your dose to find the right amount of Rosuvastatin tablets for you. The maximum daily dose of Rosuvastatin tablets is 10 or 20 mg for children aged 6 to 17 years depending on your underlying condition being treated. Take your dose once a day. Rosuvastatin **40 mg** tablet should **not** be used by children.

Taking your tablets

Swallow each tablet whole with a drink of water.

Take Rosuvastatin tablets 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 tablets that is right for you.

If you take more Rosuvastatin tablets 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 tablets.

If you forget to take Rosuvastatin tablets

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 tablets

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

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 tablets 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).
- reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome).
- Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome).

- if you have Jaundice (yellowing of the skin and eyes), Hepatitis (an inflamed liver)

Also, stop taking Rosuvastatin tablets 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*.
- lupus-like disease syndrome (including rash, joint disorders and effects on blood cells)
- muscle rupture

Common possible side effects (these may affect between 1 in 10 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 tablets (only Rosuvastatin 40 mg tablets)
- 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 (these may affect between 1 in 100 and 1 in 1,000 patients):

- 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 tablets (only Rosuvastatin 5 mg, 10 mg and 20 mg tablets)

Rare possible side effects (these may affect between 1 in 1,000 and 1 in 10,000 patients):

- Muscle damage in adults – as a precaution, stop taking Rosuvastatin 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
- Bleeding or bruising more easily than normal due to low level of blood platelets.

Very rare possible side effects (these may affect less than 1 in 10,000 patients):

- 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 may include:

- Diarrhoea (loose stools), 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.
- Rash that may occur on the skin or sores in the mouth (lichenoid drug eruption).
- Myasthenia gravis (a disease causing general muscle weakness including in some cases muscles used when breathing). Ocular myasthenia (a disease causing eye muscle weakness). Talk to your doctor if you experience weakness in your arms or legs that worsens after periods of activity, double vision or drooping of your eyelids, difficulty swallowing, or shortness of breath.

Muscle-related side effects

A study that reviewed combined results from multiple clinical trials found that statins can sometimes cause a small increase in mild muscle symptoms in the first year of statin treatment. The study also demonstrated an increase in first episode of muscle pain or weakness symptoms being more likely for intensive statin treatment compared to moderate/less intense statin treatment. However, in more than 90% of cases, the muscle-related symptoms reported were not caused by the statin itself.

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 Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Rosuvastatin tablets

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 label or blister or bottle after EXP. The expiry date refers to the last day of that month.

Blister pack: Store in the original blister packs to protect from moisture
Container pack: Keep the plastic container tightly closed to protect from moisture
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

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MODULE 1.3 PRODUCT INFORMATION
Rosuvastatin 5 mg, 10 mg, 20 mg & 40 mg Film-Coated Tablets.

What Rosuvastatin tablets contains

The active substance is Rosuvastatin. Each film-coated tablet contains 5 mg/10 mg/ 20 mg/40 mg of Rosuvastatin (as Rosuvastatin calcium).

The other ingredients are:
Tablet core: Sodium bicarbonate, precipitated calcium carbonate, lactose monohydrate, microcrystalline cellulose, crospovidone, povidone, magnesium stearate.

Tablet Film-coat:

5 mg: Opadry yellow (03K520021) containing

Hypromellose (6 cP) (E464), titanium dioxide (E171), triacetin, tartrazine aluminium lake (E102), allura red AC aluminium lake (E129) and indigo carmine aluminium lake (E132).

10 mg, 20 mg and 40 mg: Opadry pink (03K540034) containing

Hypromellose (6 cP) (E464), titanium dioxide (E171), triacetin, sunset yellow FCF aluminium lake (E110), allura red AC aluminium lake (E129) and indigo carmine aluminium lake (E132).

What Rosuvastatin tablets looks like and contents of the pack

Rosuvastatin tablets are available in blister pack and plastic container.

Pack sizes:
Blister: 7, 10, 14, 15, 20, 28, 30, 42, 50, 56, 60, 84, 90, 98 and 100 tablets
Plastic container: 30 tablets

Not all pack sizes may be marketed.

Rosuvastatin comes in four tablet strengths:

Rosuvastatin 5 mg film-coated tablets are yellow, circular, biconvex, film-coated tablets, debossed ‘5’ on one face and ‘R’ on other face, about 7 mm in diameter.
Rosuvastatin 10 mg film-coated tablets are pink, circular, biconvex, film-coated tablets, debossed ‘10’ on one face and ‘R’ on other face, about 7 mm in diameter.
Rosuvastatin 20 mg film-coated tablets are pink, circular, biconvex, film-coated tablets, debossed ‘20’ on one face and ‘R’ on other face, about 9 mm in diameter.
Rosuvastatin 40 mg film-coated tablets are pink, oval shaped, biconvex, film-coated tablets, debossed ‘40’ on one face and ‘R’ on other face, around 12 mm in length and 7 mm in width.

Marketing Authorization Holder and Manufacturer

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