APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

VUSOR 5 film-coated tablets

VUSOR 10 film-coated tablets

VUSOR 20 film-coated tablets

VUSOR 40 film-coated tablets

Rosuvastatin

Contains sugar.

VUSOR 5 contains 42,55 mg lactose monohydrate per tablet.

VUSOR 10 contains 37,35 mg lactose monohydrate per tablet.

VUSOR 20 contains 74,70 mg lactose monohydrate per tablet.

VUSOR 40 contains 149,40 mg lactose monohydrate per tablet.

Read this entire leaflet carefully before you start taking VUSOR:

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist, nurse or other health care provider.
- VUSOR has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:

1. What VUSOR is and what it is used for

2. What you need to know before you take VUSOR

3. How to take VUSOR

4. Possible side effects

5. How to store VUSOR

6. Contents of the pack and other information

1. What VUSOR is and what it is used for:

VUSOR belongs to a group of medicines called statins.

VUSOR is used together with lifestyle changes (diet, weight-loss, exercise) to reduce the amount of cholesterol (a fat-like substance) and other fatty substances in your blood.

If you are at risk of developing atherosclerotic cardiovascular disease (disease caused by the build-up of fatty deposits in your arteries), VUSOR is used to lower your risk for stroke, heart attack and the need for coronary bypass surgery.

VUSOR can be used in children and adolescents (10 to 17 years of age) and in adults (18 years and older).

2. What you need to know before you take VUSOR:

Do not take VUSOR:

- If you have known hypersensitivity (allergy) to rosuvastatin, other statins or any of the other ingredients contained in VUSOR.
- If you currently have liver disease.
- If you take a medicine called ciclosporin (used, for example, after organ transplants).
- If you have been diagnosed with myopathy (a muscle disease).
- If you are pregnant or breastfeeding (see Pregnancy and breastfeeding).
- If you have severe kidney problems.
- If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking VUSOR or other related medicines.
- If you take a medicine combination of sofosbuvir/velpatasvir/voxilaprevir (used for viral infection of the liver called hepatitis C).

In addition, do not take VUSOR 40 mg (the highest dose) if you are at risk of muscle disorders. The following conditions may increase the risk of muscle disorders:

- If you have moderate kidney problems (if in doubt, please ask your doctor).
- If you have a condition called hypothyroidism (underactive thyroid).
- 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 taking other medicines called fibrates (for high cholesterol).
- If you are of Asian origin.

Safety and efficacy have not been demonstrated in children younger than 10 years of age. VUSOR 40 mg is not suitable for use in children under 18 years of age.

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

Warnings and precautions

Special care should be taken with VUSOR

- If you have problems with your kidneys.
- If you have problems with your liver.
- 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. Tell your doctor immediately if you have unexplained muscle aches and pains especially if you feel unwell or have a fever. Also tell your doctor if you have a muscle weakness that is constant.
- If your thyroid gland is not working properly.
- If you are over 70 (as your doctor needs to choose the right starting dose of VUSOR to suit you).
- If you are taking protease inhibitors such as lopinavir/ritonavir (medicines to treat the HIV infection) (see Other medicines and VUSOR).

- 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 VUSOR can lead to serious muscle problems (rhabdomyolysis), please see Other medicines and VUSOR.
- If you have severe respiratory failure. Tell your doctor if you experience difficulty breathing, develop a non-productive cough and/or deterioration in general health (e.g. fatigue, weight loss and fever) while taking VUSOR.
- If you suffer from memory loss, forgetfulness or confusion (see Possible side effects).
- If you go into hospital or receive treatment for another condition, tell the medical staff that you are taking VUSOR.
- Serious skin reactions including Stevens-Johnson syndrome and medicine reaction with eosinophilia and systemic symptoms (DRESS) have been reported in association with VUSOR treatment. Stop using VUSOR and seek medical attention immediately if you notice any of the symptoms described in section 4.

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

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

In a small number of people, VUSOR can affect the liver. This is identified by a 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 treatment starts with VUSOR, and if needed thereafter.

While you are on VUSOR 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 VUSOR:

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

Medicines that may interact with VUSOR:

- Ciclosporin (used for example, after organ transplants) as this may increase the effect of VUSOR.
- Blood thinners e.g. warfarin (their blood thinning effect and the risk of bleeding may be increased while taken together with this medicine), ticagrelor or clopidogrel.
- Fibrates (such as gemfibrozil, fenofibrate) or any other medicine used to lower cholesterol (such as ezetimibe) as these medicines may increase the effect of VUSOR and the risk of developing serious muscle problems (see Do not take VUSOR above).
- Indigestion remedies, such as antacids (used to neutralise acid in your stomach) as these medicines may decrease the effect of VUSOR.
- Erythromycin (an antibiotic) as this may decrease the effect of VUSOR.
- Fusidic acid (an antibiotic) may increase the risk of developing serious muscle problems (see Warnings and precautions).
- An oral contraceptive (the pill) as VUSOR may increase the effect of contraceptives.
- Regorafenib (used to treat cancer) as this may increase the effect of VUSOR.
- Hormone replacement therapy as VUSOR may increase the effect of these medicines.
- Medicines used to treat viral infections, including HIV or hepatitis C infection, alone or in combination (please see Warnings and precautions above), as these medicines may increase the effect of VUSOR and may lead to an increase in the possible side effects of VUSOR: ritonavir, lopinavir, atazanavir, ombitasvir, paritaprevir, dasabuvir, simeprevir, velpatasvir, grazoprevir, elbasvir, glecaprevir, pibrentasvir, darunavir, tipranavir.
- Eltrombopag (used to treat low blood platelet counts caused by an autoimmune disorder) as this may increase the effect of VUSOR.
- Dronedarone (used to treat abnormal heart rhythm) as this may increase the effect of VUSOR.
- Itraconazole (used to treat fungal infections) as this may increase the effect of VUSOR.

If you need to take oral fusidic acid to treat a bacterial infection you will need to temporarily stop using VUSOR. Your doctor will tell you when it is safe to restart VUSOR. Taking VUSOR with fusidic acid may lead to muscle weakness, tenderness or pain (rhabdomyolysis).

Taking VUSOR with food and drink:

VUSOR may be taken with or without food.

Pregnancy and breastfeeding:

Do not take VUSOR if you are pregnant or breastfeeding. If you become pregnant while taking VUSOR stop taking it immediately and tell your doctor. Women should avoid becoming pregnant while taking VUSOR by using suitable contraception.

If you are pregnant or breastfeeding your baby please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

Driving and using machines:

VUSOR may cause dizziness. You should not drive or use machinery until you are sure that your ability to do such activities is not affected by VUSOR.

VUSOR contains lactose monohydrate:

VUSOR contains lactose. Patients who are lactose intolerant or have rare hereditary problems of galactose intolerance, Lapp-lactase deficiency or glucose-galactose malabsorption should not take VUSOR.

3. How to take VUSOR:

Do not share medicines prescribed for you with any other person.

Always take VUSOR exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are not sure. Your doctor will decide on the correct dose for you based on your individual condition and needs. The dose may need to be increased or decreased depending on your response. Do not change your dose yourself. If you have the impression that the effect of VUSOR is too strong or too weak, talk to your doctor or pharmacist.

Usual doses in adults:

Starting dose:

Your treatment with VUSOR usually starts with the 5 mg dose, even if you have taken a different statin before. The choice of your starting dose will depend upon:

- Your cholesterol levels.
- 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 starting dose of VUSOR 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 VUSOR 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. There should be a gap of 2 to 4 weeks between every dose adjustment.

The maximum daily dose of VUSOR is 40 mg. This 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.

Use in children and adolescents aged 10 to 17 years:

The dose range in children and adolescents aged 10 to 17 years is 5 mg 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 VUSOR for you. The maximum daily dose of VUSOR is 20 mg for children aged 10 to 17 years. Take your dose once a day. VUSOR 40 mg tablet should not be used by children.

Taking your tablets:

Swallow the tablets whole with a glass of water, with or without food.

Take VUSOR 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 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 VUSOR that is right for you.

If you take more VUSOR than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take VUSOR:

Take your next scheduled dose at the correct time. Do not take a double dose to make up for forgotten individual doses.

If you stop taking VUSOR:

Do not stop taking VUSOR even if you are feeling well. Talk to your doctor if you want to stop taking

VUSOR. Your cholesterol levels might increase again if you stop taking VUSOR.

4. Possible side effects:

VUSOR can have side effects.

Not all side effects reported for VUSOR are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking VUSOR, please consult your health care provider for advice.

If any of the following happens, stop taking VUSOR and tell your doctor immediately or go to the casualty department at your nearest hospital:

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

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to VUSOR. You may need urgent medical attention or hospitalisation.

Also, stop taking VUSOR and tell your doctor immediately or go the casualty department at your nearest hospital if you notice any of the following:

- Any unusual aches and pains in your muscles which go on for longer than you might expect, especially if you develop a fever or feel unwell. Unpleasant muscle effects may become a potentially life threatening muscle damage known as rhabdomyolysis. Muscle symptoms are more frequent in children

and adolescents than in adults.

- A severe stomach pain (inflamed pancreas).
- Increase in liver enzymes in the blood.
- Hepatitis (an inflamed liver).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Increased glucose levels, diabetes.
- Headache, dizziness.
- Constipation, feeling sick, stomach pain.
- Rash, itching or other skin reactions.
- Muscle pain.
- Feeling weak or a lack of energy.
- Oedema (swelling under the skin).

Less frequent side effects:

- Abnormal bleeding or bruising.
- Depression.
- Memory loss, forgetfulness, confusion.
- Damage to the nerves of your legs and arms (such as numbness).
- Disturbed sleep patterns including insomnia and nightmares.
- Fever.
- Cough, shortness of breath¸ difficulty breathing.
- Diarrhoea.
- Flushing, sensitivity to light, abnormal hair loss.

- Lupus-like disease syndrome (including rash, joint disorders and effects on blood cells).
- Muscle rupture.
- Joint pain.
- An increase in the amount of protein in the urine – this usually returns to normal on its own without having to stop taking your VUSOR tablets (only VUSOR 40 mg).
- Traces of blood in your urine.
- Decreased libido, sexual difficulties.
- Breast enlargement in men (gynaecomastia).

Side effects with unknown frequency:

- Serious blistering condition of the skin, mouth, eyes and genitals (Stevens-Johnson syndrome).
- Tendon disorders sometimes complicated by rupture.
- Serious muscle damage presenting as unexplained muscle aches and pains, feeling unwell and a fever (immune-mediated necrotising myopathy).

If you notice any side effects not listed in this leaflet, please ~~tell~~ inform your doctor or pharmacist.

Reporting of side effects:
If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of VUSOR.

5. How to store VUSOR:

Blister packs: Store at or below 25 °C. Keep the blisters in the carton until required for use.

Protect from light.

Do not use VUSOR after the expiry date which is stated on the packaging. The expiry date refers to the last day of the month.

KEEP ALL MEDICINES OUT OF THE REACH OF CHILDREN.

Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What VUSOR contains

The active substance is rosuvastatin.

The other ingredients are:

Core tablet: lactose monohydrate, microcrystalline cellulose (Type 101), crospovidone (Type A), sodium carbonate monohydrate, sodium lauryl sulphate. magnesium stearate.

Film-coating:

VUSOR 5: Opadry II yellow consisting of polyvinyl alcohol, titanium dioxide (E171), polyethylene glycol, talc, iron oxide yellow (E172).

VUSOR 10, 20, 40: Opadry II pink consisting of polyvinyl alcohol, titanium dioxide (E171), polyethylene glycol, talc, iron oxide red (E172), iron oxide yellow (E172), Allura red AC (E129), indigo carmine (E132).

What VUSOR looks like and contents of the pack:

VUSOR 5:

Yellow, round, convex shaped, coated tablet with ‘RU5’ on one side and blank on the other side.

VUSOR 10:

Pink, round, convex shaped, coated tablet with ‘RU10’ on one side and blank on the other side.

VUSOR 20:

Pink, round, convex shaped, coated tablet with ‘RU20’ on one side and blank on the other side.

VUSOR 40:

Pink, oval shaped coated tablet with ‘RU40’ on one side and blank on the other side.

VUSOR tablets are available in foil blisters of 10 tablets per strip (30 tablets per carton).

Holder of Certificate of Registration:

Teva Pharmaceuticals (Pty) Ltd.

Maxwell Office Park, Magwa Crescent West

Waterfall City, Midrand

2090

Tel.: +27 (11) 055 0200

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