

Applicant: Teva Pharmaceuticals (Pty) Ltd	Product name: VUSOR 5 / 10 / 20 / 40 OD Dosage form: Film-coated tablet
Reg. No.: 53/7.5/0268 53/7.5/0269 53/7.5/0270 53/7.5/0271	Strength: Each film-coated tablet contains rosuvastatin calcium equivalent to 5 mg, 10 mg, 20 mg or 40 mg rosuvastatin, respectively

PATIENT INFORMATION LEAFLET:

SCHEDULING STATUS: S4

VUSOR 5 OD (5 mg film-coated tablets)

VUSOR 10 OD (10 mg film-coated tablets)

VUSOR 20 OD (20 mg film-coated tablets)

VUSOR 40 OD (40 mg film-coated tablet)

Rosuvastatin calcium

Contains sugar (lactose monohydrate)

Read all of this leaflet carefully before you start taking VUSOR OD:

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- VUSOR OD 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 OD IS AND WHAT IT IS USED FOR

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3. HOW TO TAKE VUSOR OD

4. POSSIBLE SIDE EFFECTS

5. HOW TO STORE VUSOR OD

6. CONTENTS OF THE PACK AND OTHER INFORMATION

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1. WHAT VUSOR OD IS AND WHAT IT IS USED FOR:

VUSOR OD contains 5 mg, 10 mg, 20 mg or 40 mg of rosuvastatin, as rosuvastatin calcium, per film-coated tablet and belongs to the pharmacotherapeutic group called HMG-CoA reductase inhibitors.

VUSOR OD is used to reduce the risk of incidents that may cause damage to the heart muscle in patients at risk of developing heart disease as a result of build-up of fats in and on the blood vessels of the heart.

VUSOR OD is used, together with diet, to lower high levels of fats in the blood, which are called lipids, usually when changes to diet and exercise have failed to do this. VUSOR OD, in addition to diet, lowers bad cholesterol (LDL) and increases good cholesterol (HDL) in the blood.

VUSOR OD is also used to reduce total cholesterol and bad cholesterol (LDL) in adult patients with very high cholesterol and a family history of high cholesterol, either alone or together with diet and other lipid lowering treatments.

VUSOR 40 OD should only be considered in patients with severe high cholesterol and high cardiovascular risk who do not achieve their treatment goal on 20 mg of VUSOR OD or alternative therapy.

Specialist supervision is recommended when the 40 mg dose is initiated.

VUSOR OD can be used in children and adolescents (10 to 17 years of age) to reduce the total cholesterol, bad cholesterol (LDL) and lipids in patients with genetically inherited high cholesterol called heterozygous familial hypercholesterolaemia (HeFH).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE VUSOR OD:

Do not take VUSOR OD:

- if you are hypersensitive (allergic) to rosuvastatin or any of the other ingredients of VUSOR OD (listed in **section 6**)
- if you currently have a liver disease
- if you have severe kidney problems

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- if you take a medicine called ciclosporin (used, for example, after organ transplants) (see **Other medicine and VUSOR OD**)
- if you are pregnant or breastfeeding or if you are a woman of childbearing potential not using appropriate contraceptive measures (see **Pregnancy, breastfeeding and fertility**)
- if you have a muscle disease called myopathy.

Patients with the following pre-disposing conditions for a muscle disease called myopathy must not take VUSOR 40 OD (the highest dose). 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 descent.

Warnings and precautions:

Take special care with VUSOR OD:

Tell your doctor or healthcare professional before taking VUSOR OD:

- if you suffer from a condition called myasthenia gravis or ocular myasthenia with symptoms of a weakness and rapid fatigue of voluntary muscles or muscles that move the eyes and eyelids
- if you have problems with your kidneys
- if you have unexplained muscle aches and pains, muscle weakness, cramps and especially if you feel unwell or have a fever, tell your doctor immediately

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- if your thyroid gland is not working properly (hypothyroidism)
- if you have a personal or family history of hereditary muscular disorders
- if you have a previous history of muscle problems when using cholesterol lowering medicines
- if you regularly consume large amounts of alcohol
- if you are above 70 years of age
- if you are taking fibrates (cholesterol lowering medicine) please see **Other medicine and VUSOR OD**
- 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 OD can lead to serious muscle problems (rhabdomyolysis), please see **Other medicine and VUSOR OD**
- if you are taking other HMG-CoA reductase inhibitors together with fibric acid derivatives including gemfibrozil, ciclosporin, nicotinic acid, azole antifungals, protease inhibitors (such as lopinavir/ritonavir – medicines used to treat HIV infection) and macrolide antibiotics (see **Other medicines and VUSOR OD**).

VUSOR OD may cause interstitial lung disease, especially with long-term treatment. 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 OD.

In a small number of people, VUSOR OD 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 OD, and if needed thereafter.

In patients whose high cholesterol is caused by another disease, such as thyroid or kidney problems, the underlying disease should be treated prior to initiating therapy with VUSOR OD.

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While you are on VUSOR OD 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. VUSOR OD should be used with care in patients with Type 2 diabetes and in patients at risk.

Other medicines and VUSOR OD:

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

Tell your doctor if you are taking any of the following medicines:

Contraindicated combinations:

VUSOR OD should not be used together with ciclosporin (used for example, after organ transplants).

The 40 mg dose is contraindicated with concomitant use of a fibrate.

There may be a higher than usual chance of other side effects:

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 OD and the risk of developing serious muscle problems (see **Do not take VUSOR OD** above).

Fusidic acid (an antibiotic) may increase the risk of developing serious muscle problems (see **Take special care with VUSOR OD** above). If you need to take oral fusidic acid to treat a bacterial infection you will need to temporarily stop using VUSOR OD. Your doctor will tell you when it is safe to restart VUSOR OD. Taking VUSOR OD with fusidic acid may lead to muscle weakness, tenderness or pain (rhabdomyolysis).

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Medicines used to treat viral infections, including HIV or hepatitis C infection, alone or in combination (please see **Take special care with VUSOR OD** above), as these medicines may increase the effect of VUSOR OD and may lead to an increase in the possible side effects of VUSOR OD: ritonavir, lopinavir, atazanavir, ombitasvir, paritaprevir, dasabuvir, velpatasvir, grazoprevir, elbasvir, glecaprevir, pibrentasvir, darunavir, tipranavir.

Effect of VUSOR OD may be increased:

- Warfarin or clopidogrel (or any other medicine used for thinning the blood) as VUSOR OD may affect the way this medicine works; clopidogrel may increase the effect of VUSOR OD.
- Regorafenib (used to treat cancer) as this may increase the effect of VUSOR OD.
- Eltrombopag (used to treat low blood platelet counts caused by an autoimmune disorder) as this may increase the effect of VUSOR OD.
- Dronedaron (used to treat abnormal heart rhythm) as this may increase the effect of VUSOR OD.
- Itraconazole (used to treat fungal infections) as this may increase the effect of VUSOR OD.

Effect of VUSOR OD may be decreased:

- Indigestion remedies, such as antacids (used to neutralise acid in your stomach) as these medicines may decrease the effect of VUSOR OD.
- Erythromycin (an antibiotic) as this may decrease the effect of VUSOR OD.

VUSOR OD may increase the effect of other medicines:

- Oral contraceptives (the pill) as VUSOR OD may increase the effect of contraceptives.
- Hormone replacement therapy as VUSOR OD may increase the effect of these medicines.

Taking VUSOR OD with food and alcohol:

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You can take VUSOR OD with or without food.

If you regularly drink large amounts of alcohol, it may increase your risk of muscle disorders.

Pregnancy, breastfeeding and fertility:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Women of child-bearing potential should use appropriate contraceptive measures.

VUSOR OD is contraindicated in pregnancy and lactation.

Driving and using machines:

VUSOR OD may cause dizziness, therefore you should not drive or use machines until you know how VUSOR OD affects you.

It is not always possible to predict to what extent VUSOR OD may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which VUSOR OD affects them.

VUSOR OD contains lactose:

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking VUSOR OD.

3. HOW TO TAKE VUSOR OD:

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

Always take VUSOR OD exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

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Before starting treatment, your doctor should place you on a standard cholesterol-lowering diet that should continue during treatment.

The dosage range for VUSOR OD is 5 to 40 mg orally once a day. The recommended start dose is 5 mg once a day.

Your dosage will be individualised according to your cholesterol levels, your risk factors and your response to VUSOR OD-therapy. The majority of patients are controlled at the 10 mg dose. However, if necessary, dose adjustment can be made at 2 to 4 week intervals.

A 5 mg starting dose is recommended for patients of Asian ancestry and for patients requiring a smaller reduction in 'bad' cholesterol (LDL-C) to achieve treatment target.

For patients with severely high cholesterol (including genetically inherited high cholesterol), a start dose of 20 mg may be considered.

For patients with genetically inherited high cholesterol, a start dose of 20 mg once a day is recommended.

Children and adolescents 10 to 17 years of age:

In children and adolescents with genetically inherited high cholesterol, the usual dose range is 5 to 20 mg orally once daily.

Special populations:

Use in the elderly:

The usual dose range applies.

Dosage in patients with renal insufficiency:

The starting dose applies in patients with mild to moderate renal impairment.

For patients with severe renal impairment the dose of VUSOR OD should not exceed 10 mg once daily.

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Dosage in patients with hepatic insufficiency:

The usual starting dose applies in patients with mild to moderate hepatic impairment. Patients with severe hepatic impairment should start therapy with VUSOR 5 OD, doses above 10 mg should be carefully considered.

Race:

A 5 mg starting dose of VUSOR OD should be considered for Asian patients.

Your doctor will tell you how long your treatment with VUSOR OD will last. It may take weeks or months of treatment for you to see any improvement in your symptoms and your symptoms might even worsen when VUSOR OD is started. Do not stop treatment early.

If you have the impression that the effect of VUSOR OD is too strong or too weak, tell your doctor or pharmacist.

If you take more VUSOR OD 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 OD:

Do not take a double dose to make up for the forgotten individual doses.

4. POSSIBLE SIDE EFFECTS:

VUSOR OD can have side effects.

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

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If any of the following happens, stop taking VUSOR OD 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)
- blistering of the skin, mouth and eyes (Steven-Johnson syndrome)
- jaundice (yellowing of the skin and eyes).

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- symptoms of myasthenia gravis and ocular myasthenia which include weakness in the arm and leg muscles, double vision, drooping eyelids, trouble focusing and difficulties with speech and chewing
- 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
- 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)
- 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.

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Tell your doctor if you notice any of the following:

Frequent side effects:

- increased glucose levels, diabetes
- headache, dizziness
- constipation, nausea, stomach pain
- muscle pain
- feeling weak or a lack of energy.

Less frequent side effects:

- abnormal bleeding or bruising
- memory loss
- numbness, tingling, loss of sensation in the arms and legs, burning feeling in the hands or feet (polyneuropathy)
- rash, itching or other skin reactions
- oedema (swelling under the skin)
- cough, shortness of breath, difficulty breathing
- lupus-like disease syndrome (including rash, joint disorders and effects on blood cells)
- muscle rupture
- joint pain
- traces of blood in your urine
- breast enlargement in men (gynaecomastia).

Side effects with unknown frequency:

- depression

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- diarrhoea
- an increase in the amount of protein in the urine
- numbness and tingling in hands or feet (peripheral neuropathy).

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

Reporting of side effects:

If you get side effects, talk to your doctor, pharmacist or nurse. 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 this medicine.

5. HOW TO STORE VUSOR OD:

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Store at or below 30 °C.

Store in the original container.

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 OD contains:

VUSOR 5 OD: Each film-coated tablet contains 5 mg rosuvastatin (as rosuvastatin calcium).

VUSOR 10 OD: Each film-coated tablet contains 10 mg rosuvastatin (as rosuvastatin calcium).

VUSOR 20 OD: Each film-coated tablet contains 20 mg rosuvastatin (as rosuvastatin calcium).

VUSOR 40 OD: Each film-coated tablet contains 40 mg rosuvastatin (as rosuvastatin calcium).

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The other ingredients of the tablet core are microcrystalline cellulose, lactose monohydrate, crospovidone Type B, Hydroxypropylcellulose, sodium hydrogen carbonate and magnesium stearate.

The other ingredients of the tablet coating are lactose monohydrate, hypromellose 6 cP (HPMC 2910), titanium dioxide (E171), triacetin, ferric oxide yellow (E172) (5 mg tablet) and ferric oxide red (E172) (10 mg, 20 mg and 40 mg tablets).

What VUSOR OD looks like and contents of the pack:

VUSOR 5 OD: Round biconvex, yellow coloured film-coated tablet plain on both sides with a diameter of 5,5 mm $\pm$ 0,3 mm.

VUSOR 10 OD: Round biconvex, pink coloured film-coated tablet with break line on one side and plain on the other side with a diameter of 7,0 mm $\pm$ 0,3 mm.

VUSOR 20 OD: Round biconvex, pink coloured film-coated tablet with break line on one side and plain on the other side with a diameter of 9,0 mm $\pm$ 0,3 mm.

VUSOR 40 OD: Oval biconvex, pink coloured film-coated tablet with break line on one side and plain on the other side with dimensions of 11,5 mm $\pm$ 0,3 mm in length and 7,0 mm $\pm$ 0,3 mm in width.

VUSOR OD film-coated tablets are packed in:

OPA/Al/PVC-Aluminium blisters strips or PVC/PVDC-Aluminium blister strips in an outer carton. Pack sizes of 7, 14, 15, 20, 28, 30, 42, 50, 56, 60, 84, 90, 98 and 100 tablets.

HDPE bottles with PP caps with desiccant or HDPE bottles with child resistant PP closure with canister with desiccant. Pack sizes 30, 100 or 500 tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration:

Teva Pharmaceuticals (Pty) Ltd.

Maxwell Office Park

Magwa Crescent West

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