SCHEDULING STATUS S4

Rosuvastatin 5 Adco, 5 mg film-coated tablets
Rosuvastatin 10 Adco, 10 mg film-coated tablets
Rosuvastatin 20 Adco, 20 mg film-coated tablets
Rosuvastatin 40 Adco, 40 mg film-coated tablets

Rosuvastatin calcium
Contains sugar (lactose monohydrate)

Read all of this leaflet carefully before you start taking Rosuvastatin Adco.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, nurse or other health care provider.
- Rosuvastatin Adco 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 Rosuvastatin Adco is and what it is used for
2. What you need to know before you take Rosuvastatin Adco
3. How to take Rosuvastatin Adco
4. Possible side effects
5. How to store Rosuvastatin Adco
6. Contents of the pack and other information

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

Rosuvastatin Adco 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.
Rosuvastatin Adco 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.
Rosuvastatin Adco 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.
Rosuvastatin Adco, in addition to diet, lowers “bad” cholesterol (LDL) and increases “good” cholesterol (HDL) in the blood.
Rosuvastatin Adco 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.

Rosuvastatin 40 Adco 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 Rosuvastatin Adco or alternative therapy.

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

Do not take Rosuvastatin Adco:

- if you are hypersensitive (allergic) to rosuvastatin or any of the other ingredients of Rosuvastatin Adco (listed in section 6)
- if you currently have a liver disease
- if you have severe kidney problems
- if you take a medicine called ciclosporin (used, for example, after organ transplants) (see **Other Medicines and Rosuvastatin Adco**)
- 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**)

Patients with the following pre-disposing conditions for a muscle disease called myopathy must not take Rosuvastatin 40 Adco (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 Rosuvastatin Adco:

- if you have problems with your kidneys
- If you have problems with your liver
- 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 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 Rosuvastatin Adco** 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 Adco can lead to serious muscle problems (rhabdomyolysis), please see **Other medicine and Rosuvastatin Adco**

- 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 medicine and Rosuvastatin Adco**).

Rosuvastatin Adco 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 Rosuvastatin Adco.

In a small number of people, Rosuvastatin Adco 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 Rosuvastatin Adco, 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 Rosuvastatin Adco.

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

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

Tell your doctor if you are taking any of the following:
Contraindicated combinations
Rosuvastatin Adco 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 Rosuvastatin Adco and the risk of developing serious muscle problems (see **Do not take Rosuvastatin Adco** above).
Fusidic acid (an antibiotic) may increase the risk of developing serious muscle problems (see **Take special care with Rosuvastatin Adco** above). If you need to take oral fusidic acid to treat a bacterial infection you will need to temporarily stop using Rosuvastatin Adco. Your

doctor will tell you when it is safe to restart Rosuvastatin Adco. Taking Rosuvastatin Adco with fusidic acid may lead to muscle weakness, tenderness or pain (rhabdomyolysis).

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

Effect of Rosuvastatin Adco may be increased

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

Effect of Rosuvastatin Adco may be decreased

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

Rosuvastatin Adco may increase the effect of other medicines

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

Rosuvastatin Adco with food and alcohol

You can take Rosuvastatin Adco 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 Rosuvastatin Adco. Women of child-bearing potential should use appropriate contraceptive measures.
Rosuvastatin Adco is contraindicated in pregnancy and lactation.

Driving and using machines
Rosuvastatin Adco may cause dizziness, therefore you should not drive or use machines until you know how Rosuvastatin Adco affects you.

It is not always possible to predict to what extent Rosuvastatin Adco 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 Rosuvastatin Adco affects them.

Rosuvastatin Adco contains lactose monohydrate
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Rosuvastatin Adco

Do not share medicines prescribed for you with any other person.
Always take Rosuvastatin Adco exactly as your doctor has told you. You should check with your doctor or pharmacist if you are unsure.

Before starting treatment, your doctor should place you on a standard cholesterol-lowering diet that should continue during treatment.
The dosage range for Rosuvastatin Adco is 5 - 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 Rosuvastatin Adco-therapy. The majority of patients are controlled at the 10 mg dose. However, if necessary, dose adjustment can be made at 2 – 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 - 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 Rosuvastatin Adco should not exceed

10 mg once daily.

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 Rosuvastatin 5 Adco, doses above 10 mg should be carefully considered.

Race
A 5 mg starting dose of Rosuvastatin Adco should be considered for Asian patients.

Your doctor will tell you how long your treatment with Rosuvastatin Adco 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 Rosuvastatin Adco is started. Do not stop treatment early.
If you have the impression that the effect of Rosuvastatin Adco is too strong or too weak, tell your doctor or pharmacist.

If you take more Rosuvastatin Adco than you should
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take Rosuvastatin Adco
Do not take a double dose to make up for a forgotten dose.

4. Possible side effects

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

If any of the following happens, stop taking Rosuvastatin Adco 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 ng 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 reaction to Rosuvastatin Adco. 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:

- 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.

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)
- 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 of unknown frequency:
- Cough, shortness of breath¸ difficulty breathing
- Depression
- 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 Rosuvastatin Adco

- Store at or below 30 °C.
- Store in the original package in order to protect from light.
- **STORE ALL MEDICINES OUT OF REACH OF CHILDREN**.
- Do not use this medicine after the expiry date (EXP) which is stated on the box/blisters .
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What Rosuvastatin Adco contains

The active substance is rosuvastatin.

Rosuvastatin Adco 5: Each film-coated tablet contains 5 mg rosuvastatin (as rosuvastatin calcium)

Rosuvastatin 10 Adco: Each film-coated tablet contains 10 mg rosuvastatin (as rosuvastatin calcium)

Rosuvastatin 20 Adco: Each film-coated tablet contains 20 mg rosuvastatin (as rosuvastatin calcium)

Rosuvastatin 40 Adco: Each film-coated tablet contains 40 mg rosuvastatin (as rosuvastatin calcium)

The other ingredients are:

Tablet core : cellulose microcrystalline, type A, crospovidone type A, lactose monohydrate and magnesium stearate .

Tablet coating layer: lactose monohydrate, hypromellose (E464), triacetin (E1518), titanium dioxide (E171), quinoline yellow aluminium lake (E104) (5 mg tablets), allura red aluminium lake (E129) (10 mg tablets), carmine (E120) (20 mg tablets), sunset yellow aluminium lake (E 110) and ponceau aluminium lake (E 124) (40 mg tablets).

What Rosuvastatin Adco looks like and contents of the pack

Rosuvastatin Adco is packed in:

Blister-pack type packaging, consisting of laminate foil and aluminium foil. Each blister contains 7 or 10 tablets. The secondary packaging is a cardboard box containing 3 or 4 blisters (28 or 30 tablets) and a leaflet.

Rosuvastatin Adco comes in four tablet strengths:

Rosuvastatin 5 Adco: Round, biconvex, yellow film-coated tablets, 6 mm in diameter, debossed with "5" on one side.

Rosuvastatin 10 Adco: Round, biconvex, light-pink film-coated tablets, 7 mm in diameter, debossed with "10" on one side.

Rosuvastatin 20 Adco: Round, biconvex, dark-pink film-coated tablets, 9 mm in diameter, debossed with "20" on one side.

Rosuvastatin 40 Adco: Round, biconvex, red film-coated tablets, 10 mm in diameter,

debossed with “40” on one side.

Holder of Certificate of Registration
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