PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

ROSUVASTATIN UNICORN 5 (film-coated tablets)

ROSUVASTATIN UNICORN 10 (film-coated tablets)

ROSUVASTATIN UNICORN 20 (film-coated tablets)

ROSUVASTATIN UNICORN 40 (film-coated tablets)

Rosuvastatin calcium

Each ROSUVASTATIN UNICORN 5 mg tablet contains sugar (anhydrous lactose 57,920 mg) and mannitol (0,150 mg).
Each ROSUVASTATIN UNICORN 10 mg tablet contains sugar (anhydrous lactose 52,920 mg and mannitol (0,150 mg).
Each ROSUVASTATIN UNICORN 20 mg tablet contains sugar (anhydrous lactose 105,840 mg) and mannitol (0,300 mg).
Each ROSUVASTATIN UNICORN 40 mg tablet contains sugar (anhydrous lactose 211,680 mg) and mannitol (0,600 mg).

Read all of this leaflet carefully before you start taking ROSUVASTATIN UNICORN.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- ROSUVASTATIN UNICORN 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 UNICORN is and what it is used for

2. What you need to know before you take ROSUVASTATIN UNICORN

3. How to take ROSUVASTATIN UNICORN

4. Possible side effects

5. How to store ROSUVASTATIN UNICORN

6. Contents of the pack and other information

1. What ROSUVASTATIN UNICORN is used for

ROSUVASTATIN UNICORN belongs to a group of medicines called statins.

ROSUVASTATIN UNICORN is used to lower cholesterol and other lipids (fats) in the blood and may help prevent medical problems caused by cholesterol such as heart disease.

ROSUVASTATIN UNICORN is used in adults, adolescents and children 10 years or older to treat high cholesterol.

2. What you need to know before you take ROSUVASTATIN UNICORN

Do not take ROSUVASTATIN UNICORN:

- If you are allergic to rosuvastatin or any of the other ingredients of ROSUVASTATIN UNICORN (see “Contents of the pack and other information”).
- If you have any liver problems or have ever had a disease which affected your liver.
- If you have any kidney problems.
- If you are receiving treatment with ciclosporin (used in organ transplants).
- If you take a drug combination of sofosbuvir/velpatasvir/voxilaprevir (used for viral infection of the liver called hepatitis C).
- If you suffer from myopathy (a condition that can cause pain or weakness in your muscles).
- If you are pregnant, planning to become pregnant or breastfeeding. Women should avoid becoming pregnant while taking ROSUVASTATIN UNICORN by using suitable contraception.

- If you have repeated or unexplained muscle aches or pain or a family history of muscle disorders.

Do not take the 40 mg dose if you have had any of the following conditions:

- If you have kidney problems.
- If you have a thyroid disorder (hypothyroidism).
- 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 you are using medicines that can increase blood levels of rosuvastatin (see “Other medicines and ROSUVASTATIN UNICORN”).
- If you are of Asian origin.
- If you are taking other medicines called fibrates to lower your cholesterol.

Take special care with ROSUVASTATIN UNICORN:

Tell your doctor or health care professional before taking ROSUVASTATIN UNICORN:

- 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 have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking ROSUVASTATIN UNICORN or other related medicines. Serious skin

reactions including Stevens-Johnson syndrome and Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) have been reported in association with ROSUVASTATIN UNICORN treatment. Stop using ROSUVASTATIN UNICORN and seek medical attention immediately if you notice any of the symptoms described in section 4.

- 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.
- If you take medicines used to treat the HIV infection e.g. ritonavir with lopinavir and/or atazanavir.
- If you are taking or have taken in the last 7 days antibiotics containing fusidic acid. The combination of fusidic acid and ROSUVASTATIN UNICORN can lead to serious muscle problems (rhabdomyolysis), please see “Other medicines and ROSUVASTATIN UNICORN”.
- If you are over 70 (as your doctor needs to choose the right start dose of ROSUVASTATIN UNICORN 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 UNICORN to suit you.
- ROSUVASTATIN UNICORN can cause liver problems. 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 UNICORN.
- While you are taking ROSUVASTATIN UNICORN 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.
- If you have or have had myasthenia gravis (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).

Children and adolescents

- In a study conducted in children and adolescents between 10 and 17 years of age taking rosuvastatin over a 1 year period, no effect on growth, weight, Body Mass Index (BMI) or sexual maturation was detected.
- ROSUVASTATIN UNICORN 40 mg tablets are not suitable for use in children and adolescents below 18 years of age.

Other medicines and ROSUVASTATIN UNICORN

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

The following medicines cause an interaction when used in combination with ROSUVASTATIN UNICORN:

- Ciclosporin (used for example, after organ transplants).
- Warfarin, clopidogrel, ticagrelor (or any other medicine used for thinning the blood).
- Fibrates (such as gemfibrozil, fenofibrate) or any other medicine used to lower cholesterol (such as ezetimibe) and transporter protein inhibitors.
- Indigestion remedies “antacids” (used to neutralise acid in your stomach).
- Erythromycin (an antibiotic).
- Fusidic acid (an antibiotic which can be given orally or by injection or may be used topically in creams and eye drops). If you need to take fusidic acid to treat a bacterial infection you will need to temporarily stop using ROSUVASTATIN UNICORN. Your doctor will tell you when it is safe to restart. Taking ROSUVASTATIN UNICORN with fusidic acid may rarely lead to muscle weakness, tenderness or pain (rhabdomyolysis). See more information regarding rhabdomyolysis in section 4.

- Oral contraceptives (the pill).
- Hormone replacement therapy.
- Any of the following medicines 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.

The effects of these medicines could be changed by ROSUVASTATIN UNICORN or they could change the effect of ROSUVASTATIN UNICORN.

ROSUVASTATIN UNICORN with food, drink and alcohol

ROSUVASTATIN UNICORN can be taken with or without food.
Avoid taking alcohol when taking ROSUVASTATIN UNICORN as it may increase dizziness.

Pregnancy, breastfeeding and fertility

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

ROSUVASTATIN UNICORN should not be used if you are pregnant or breastfeeding your baby.
If you become pregnant while taking ROSUVASTATIN UNICORN stop taking it immediately and tell your doctor.
Women of child-bearing age should avoid becoming pregnant while taking ROSUVASTATIN UNICORN by using appropriate contraception.

Driving and using machines

ROSUVASTATIN UNICORN may cause dizziness. Make sure that you are alert before driving, operating machinery or performing any other tasks, which could be dangerous.

ROSUVASTATIN UNICORN contains lactose

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 UNICORN.

3. How to take ROSUVASTATIN UNICORN

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

Adults:

The dose range for ROSUVASTATIN UNICORN is 5 to 40 mg orally once a day. The usual starting dose is 5 mg.

Children and adolescents 10 to 17 years of age:

In children and adolescents with heterozygous familial hypercholesterolaemia the usual dose range is 5 to 20 mg orally once daily. The usual starting dose is 5 mg. ROSUVASTATIN UNICORN 40 mg tablets should not be used in children and adolescents below 18 years of age.

Depending on your condition, your doctor will decide on the correct dose for you.

ROSUVASTATIN UNICORN may be taken at any time of the day, with or without food.

You should be placed on a standard cholesterol-lowering diet and exercise programme that should continue during treatment.

Your doctor will tell you how long your treatment with ROSUVASTATIN UNICORN will last. Do not stop treatment early if you have the impression that the effect of ROSUVASTATIN UNICORN is too strong or too weak, tell your doctor or pharmacist.

If you take more ROSUVASTATIN UNICORN 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 ROSUVASTATIN UNICORN

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

4. Possible side effects

ROSUVASTATIN UNICORN can have side effects.

Not all side effects reported for ROSUVASTATIN UNICORN are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking ROSUVASTATIN UNICORN, please consult your doctor, pharmacist or other health care professional for advice.

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

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Yellowing of the skin and eyes and dark coloured or blood in the urine.
- A rare skin condition with severe blisters, skin peeling, bleeding or ulcers of the lips, eyes, mouth, throat, nose and genitals, a condition called Stevens-Johnson Syndrome (SJS). These serious skin rashes can be preceded by fever and flu-like symptoms.
- Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome).

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to ROSUVASTATIN UNICORN. 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:

- Chest pain.
- Difficulty breathing.
- Rhabdomyolysis (a breakdown of muscle tissue) which may occasionally cause kidney problems.
- Lupus-like disease syndrome (including rash, joint disorders and effects on blood cells).

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

Tell your doctor if you notice any of the following:

The following side effects have frequently been reported:

- Diabetes mellitus, or sugar diabetes, where the level of sugar in the blood is too high. Certain cells of the pancreas fail to produce normal amounts of a chemical called insulin. This causes sugar from food to pass through the system and be excreted in the urine. This is more likely if you have high levels of sugars and fats in your blood, are overweight and have high blood pressure. Symptoms include excessive thirst, the passing of a greatly increased amount of urine, increase in appetite with a loss of weight, feeling tired, drowsy, weak, depressed, irritable and generally unwell
- Headache
- Dizziness
- Diarrhoea
- Abdominal pain
- Constipation

- Vomiting
- Nausea
- Unusual tiredness or weakness
- Muscle aches and pain (myalgia)

The following side effects have been reported less frequently:

- Low blood platelet count as determined by blood tests which can lead one to bleed or bruise easily
- Damage to nerves, memory loss
- High blood pressure
- Swelling including the hands, feet and ankles
- Runny or blocked nose, sneezing, facial pressure or pain, cough, sinusitis
- Inflammation of the pancreas, indigestion, gastritis (a stomach problem which may result in pain, nausea, vomiting, vomiting blood, and blood in the bowel motions)
- Increased liver enzymes as determined by blood tests
- Aching muscles, muscle tenderness or weakness, not caused by exercise may also lead to inflammation of the muscles
- Painful or swollen joints
- Flu syndrome
- Breast enlargement in men

The following side effects have been reported with unknown frequency:

- Depression
- Sleep disturbances (including trouble sleeping (insomnia) and nightmares)
- Tendon disorders, sometimes complicated by rupture
- Signs of necrosis, or cell death, in the muscles, which causes weakness and fatigue (immune-mediated necrotising myopathy)
- Swelling (oedema)

- Protein in urine
- Abnormal laboratory results (blood or protein found in urine or high levels of creatine kinases)
- 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

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 ROSUVASTATIN UNICORN.

Suspected side effects can also be reported directly to the Holder of the Certificate of Registration (HCR) via the link: https://pvi1j.solutions.iqvia.com or the e-mail address, adverse.event.sac@sandoz.com.

5. How to store ROSUVASTATIN UNICORN

Store at or below 30 °C in a cool, dry place.

Protect from light/moisture.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

6. Contents of the pack and other information

What ROSUVASTATIN UNICORN contains

ROSUVASTATIN UNICORN 5: Each film-coated tablet contains 5,198 mg of rosuvastatin calcium equivalent to 5 mg of rosuvastatin.

ROSUVASTATIN UNICORN 10: Each film-coated tablet contains 10,396 mg rosuvastatin calcium equivalent to 10 mg of rosuvastatin.

ROSUVASTATIN UNICORN 20: Each film-coated tablet contains 20,791 mg rosuvastatin calcium equivalent to 20 mg of rosuvastatin.

ROSUVASTATIN UNICORN 40: Each film-coated tablet contains 41,583 mg rosuvastatin calcium equivalent to 40 mg of rosuvastatin.

Inactive ingredients in the tablet are:

Anhydrous lactose, maize starch dried, silica colloidal anhydrous, silicified microcrystalline cellulose (prosolv SMCC90), sodium stearyl fumarate, talc.

Inactive ingredients in the tablet coating are:

Ferric oxide red E172, ferric oxide yellow E172, hypromellose (2910), macrogol 6000, mannitol, talc, titanium dioxide E171.

What ROSUVASTATIN UNICORN looks like and contents of the pack

ROSUVASTATIN UNICORN 5: Light brown, round, film-coated tablets with “RSV 5” debossed on one side.

ROSUVASTATIN UNICORN 10: Brown, round, film-coated tablets with “RSV 10” debossed on one side.

ROSUVASTATIN UNICORN 20: Brown, round, film-coated tablets with “RSV 20” debossed on one side.

ROSUVASTATIN UNICORN 40: Brown, round, film-coated tablets with “RSV 40” debossed on one side.

ROSUVASTATIN UNICORN 5: 5 mg film-coated tablets packed into Al/Al blister packaging.
Pack size: 30 tablets.
ROSUVASTATIN UNICORN 10: 10 mg film-coated tablets packed into Al/Al blister packaging.
Pack size: 30 tablets.
ROSUVASTATIN UNICORN 20: 20 mg film-coated tablets packed into Al/Al blister packaging.
Pack size: 30 tablets.
ROSUVASTATIN UNICORN 40: 40 mg film-coated tablets packed into Al/Al blister packaging.
Pack size: 30 tablets.
Blisters are packed into a carton, and a professional information / patient information leaflet is enclosed.

Holder of Certificate of Registration

Sandoz SA (Pty) Ltd[1]
Magwa Crescent West
Waterfall City
Jukskei View
Midrand
2090

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Access to the corresponding Professional Information

Not applicable.

[1]Company Reg. No.: 1990/001979/07