PATIENT INFORMATION LEAFLET

ROSUZET FILM-COATED TABLETS

SCHEDULING STATUS: **S4**

ROSUZET 5 mg/10 mg (film-coated tablets)

ROSUZET 10 mg/10 mg (film-coated tablets)

ROSUZET 20 mg/10 mg (film-coated tablets)

ROSUZET 40 mg/10 mg (film-coated tablets)

Active substances: Rosuvastatin/Ezetimibe

Contains sugar: Each Rosuzet 5 mg/10 mg, 10 mg/10 mg, 20 mg/10 mg film-coated tablet contains 200,5 mg of lactose monohydrate and each Rosuzet 40 mg/10 mg film-coated tablet contains 205,54 mg of lactose monohydrate.

Contains sodium: Each Rosuzet 5 mg/10 mg, 10 mg/10 mg, 20 mg/10 mg and 40 mg/10 mg film-coated tablet contains 3,00 mg of sodium.

Read all of this leaflet carefully before you start taking ROSUZET

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- ROSUZET 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 ROSUZET is and what it is used for

2. What you need to know before you take ROSUZET
3. How to take ROSUZET
4. Possible side effects
5. How to store ROSUZET
6. Contents of the pack and other information.

1. What ROSUZET is and what it is used for

ROSUZET contains two different active substances in one tablet. One of the active substances is rosuvastatin, belonging to the group of so-called statins and the other active substance is ezetimibe.

ROSUZET is a medicine used in adult patients to lower levels of total cholesterol, “bad” cholesterol (LDL cholesterol) and fatty substances called triglycerides in the blood. In addition, it also raises levels of “good” (HDL cholesterol). This medicine works to reduce your cholesterol in two ways: it reduces the cholesterol absorbed in your digestive tract, as well as the cholesterol your body makes by itself.

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.

ROSUZET is used in patients whose cholesterol levels cannot be controlled by a cholesterol lowering diet alone. You should stay on your cholesterol lowering diet while taking this medicine. Your doctor may prescribe ROSUZET if you are already taking both rosuvastatin and ezetimibe at the same dose level.

ROSUZET is used if you have:

- A raised cholesterol level in your blood (primary hypercholesterolemia)

- Heart disease, ROSUZET reduces the risk of heart attack, stroke, surgery to increase heart blood flow, or hospitalization for chest pain.

ROSUZET does not help you lose weight.

2. What you need to know before you take ROSUZET

Do not take ROSUZET if you

- Are allergic to rosuvastatin, ezetimibe or any of the other ingredients of ROSUZET (listed in section **6**).
- Have liver disease.
- Have severe kidney problems.
- Have repeated or unexplained muscle aches or pains (myopathy).
- Take a medicine called ciclosporin (for example, used after organ transplants).
- Are pregnant or breast-feeding. If you become pregnant while taking ROSUZET stop taking it immediately and tell your doctor. Women should avoid becoming pregnant while taking this medicine by using suitable contraceptive measures.
- If you are taking an antibiotic medicine to treat infection, called fusidic acid.

In addition, do not take ROSUZET 40 mg/10 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 (hypothyroidism).
- If you have had any repeated or unexplained muscle aches or pains.
- If you have a personal or family history of muscle problems, or a 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 (see section "Other medicines and ROSUZET").

If any of the above applies to you (or you are in doubt), please contact your doctor.

Warnings and precautions

Talk to your doctor or pharmacist before taking ROSUZET if you:

- Have problems with your kidneys.
- Have problems with your liver.
- Have had repeated or unexplained muscle aches or pains.
- Have 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.
- Are of Asian origin (Japanese, Chinese, Filipino, Vietnamese, Korean and Indian). Your doctor needs to choose the right dose to suit you.
- Take medicines used to treat infections, including HIV or hepatitis C infection e.g., Lopinavir, ritonavir, atazanavir, simeprevir, ombitasvir, paritaprevir, dasabuvir, velpatasvir, grazoprevir, elbasvir, glecaprevir and/or pibrentasvir.
- Have severe respiratory failure.
- Take other medicines called fibrates to lower your cholesterol. Please see "Other medicines and Rosuzet.
- Are due to have an operation. You may need to stop taking ROSUZET for a short time.
- Regularly drink large amounts of alcohol.
- Suffer from hypothyroidism, where your thyroid gland is underactive.
- Are over 70 years (your doctor needs to choose the right dose of ROSUZET to suit 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 ROSUZET can lead to serious muscle problems (rhabdomyolysis).
- Are taking regorafenib (a medicine used to treat cancer).
- If you suffer from nightmares, sleepwalking, abnormal dreaming or movement during sleep as ROSUZET may aggravate these symptoms.

If any of the above applies to you (or if you are not sure): check with your doctor or pharmacist before you start taking any dose of this medicine.

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 regularly carry out this blood test (liver function test) during treatment with this medicine. It is. important to go to the doctor for the prescribed laboratory checks

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

The use of this medicine is not suitable for use in children and adolescents under the age of 18 years.

Other medicines and ROSUZET

Always tell your healthcare provider 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:

- Ciclosporin (e.g., used after organ transplants to prevent rejection of the transplanted organ.

The effect of rosuvastatin is increased if used together with ciclosporin). **Do not take** ROSUZET while taking ciclosporin.

- Blood thinners (e.g., warfarin, acenocoumarol, fluindione or clopidogrel). Their blood thinning effect and the risk of bleeding may be increased while taken together with this medicine.
- Other medicines to lower your cholesterol called fibrates (e.g., gemfibrozil and other fibrates).
- Cholestyramine (a medicine used for lowering cholesterol), because it affects the way ezetimibe works.
- Regorafenib (used to treat cancer).
- Any of the following medicines used to treat viral infections, including HIV or hepatitis C infection: ritonavir, lopinavir, atazanavir, simeprevir, ombitasvir, paritaprevir, dasabuvir, velpatasvir, grazoprevir, elbasvir, glecaprevir, pibrentasvir.
- Indigestion remedies containing aluminium and magnesium (used to neutralise acid in your stomach; they decrease the plasma level of rosuvastatin).
- Erythromycin (an antibiotic).
- Fusidic acid. 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 ROSUZET. Taking this medicine with fusidic acid may lead to muscle weakness, tenderness or pain (rhabdomyolysis).
- An oral contraceptive (the pill).
- Hormone replacement therapy (increased hormone levels in the blood).
- Colchicine, as it can cause muscle breakdown and abnormalities with skeletal muscle when taken together with ROSUZET and therefore caution should be advised.
- Daptomycin, as there is an increased risk of muscle breakdown and abnormalities with skeletal muscle when ROSUZET is taken together with daptomycin.
- Ticagrelor, as there have been cases where high risk patients such as the elderly have reported cases of muscle breakdown when taking ROSUZET together with ticagrelor. Ticagrelor causes worsening of the functioning of the kidneys, which causes the level of

rosuvastatin, as contained in ROSUZET, in the blood to rise which thereby causes an increase in muscle breakdown.

If you go into hospital or receive treatment for another condition, tell the medical staff that you are taking ROSUZET.

Pregnancy, breastfeeding and fertility

Do not take ROSUZET if you are pregnant, are trying to get pregnant or think you may be pregnant. If you get pregnant while taking this medicine, stop taking it immediately and tell your doctor. Women should use contraceptive measures during their treatment with this medicine.
Do not take ROSUZET if you are breast-feeding, because it is not known if the medicine is passed into breast milk.

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

Driving and using machines

This medicine is not expected to interfere with your ability to drive or to use machinery. However, it should be considered that some people get dizzy after taking this medicine. If you get dizzy you should not drive or use machines.

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

ROSUZET contains lactose and sodium

ROSUZET contains lactose. Patients with the rare hereditary conditions of lactose or galactose

intolerance should not take ROSUZET.

ROSUZET contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium-free’.

3. How to take ROSUZET

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

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

You should continue being on a low-cholesterol diet and doing exercises while taking ROSUZET.

The recommended dose for adults is to take one tablet a day.

You can take it at any time of the day, with or without food. Swallow each tablet whole with a drink of water.

Take your tablet at the same time every day.

This medicine is not suitable for starting treatment. Starting treatment or dose change, if necessary, should only be done by giving the active substances separately. After setting the appropriate doses, a switch to ROSUZET of the appropriate strength is then possible.

If you plan to take ROSUZET along with another medicine for lowering cholesterol containing the active ingredient cholestyramine or any other bile acid sequestrant, you should take ROSUZET at least 2 hours before or 4 hours after taking the bile acid sequestrant.

Regular cholesterol checks

It is important to go back to your doctor for regular cholesterol checks to make sure your cholesterol levels are controlled.

If you take more ROSUZET than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre because you might need medical help.

In the event of overdosage the side effects listed under section 4 (possible side effects) can be experienced.

If you forget to take ROSUZET

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

If you stop taking ROSUZET

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

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

ROSUZET can have side effects.

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

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

- Swelling of the face, lips, tongue and/or throat, difficulty in swallowing or breathing and a severe itching of the skin (with raised lumps).

- Serious blistering condition of the skin, mouth, eyes and genitals (Stevens-Johnson syndrome).

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

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

- Unexplained muscle pains, tenderness, or weakness which persist for long periods. Muscle problems can be serious and may become a potentially life-threatening condition (rhabdomyolysis).

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

Frequent side effects:

- headache
- constipation
- feeling sick
- feeling weak
- dizziness
- diabetes
- stomachache
- diarrhoea
- flatulence (excess gas in the intestinal tract)
- feeling tired
- elevations in some liver enzymes (transaminases)
- an increase in the amount of protein in the urine.

Less frequent side effects:

- rash, itching, hives
- elevations in blood creatine kinase (indicates muscle damage)
- cough
- indigestion
- heartburn
- joint pain
- muscle spasms
- neck pain
- decreased appetite
- pain
- chest pain
- hot flush
- high blood pressure
- tingling sensation
- dry mouth
- inflammation of the stomach
- back pain
- muscle weakness
- pain in arms and legs
- swelling (especially in the hands and feet)
- an increase in the amount of protein in the urine
- inflammation of the pancreas, which causes a severe stomach pain which can extend to the back
- reduction in blood platelets, which may cause bruising/bleeding (thrombocytopenia)
- lupus-like disease syndrome (including rash, joint disorders and effects on blood cells)
- muscle rupture
- jaundice (yellowing of the skin and eyes)

- inflammation of the liver (hepatitis)
- traces of blood in your urine
- damage to the nerves of your legs and arms (such as numbness)
- memory loss
- breast enlargement in men (gynecomastia).

Frequency not known:

- shortness of breath
- oedema (swelling)
- sleep disturbances, including insomnia and nightmares
- sexual difficulties
- depression
- breathing problems including persistent cough and/or shortness of breath
- tendon injury
- muscle weakness that is constant
- raised red rash, sometimes with target shaped lesions (erythema multiforme)
- muscle tenderness
- gallstones or inflammation of the gallbladder (which may cause stomachache, nausea, vomiting).

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

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8 or by e-mail: drugsafety@cipla.com or telephone: 080 222 6662 (toll free). By reporting side effects, you can help provide more information on the safety of ROSUZET.

5. How to store ROSUZET

Store at or below 25 °C.

Store in the original package in order to protect from light and moisture.

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 carton box and the blister.

The expiry date refers to the last day of that month.

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 to protect the environment.

6. Contents of the pack and other information

What ROSUZET contains

The active substances are rosuvastatin (as rosuvastatin calcium) and ezetimibe.

ROSUZET 5 mg/10 mg: Each film-coated tablet contains rosuvastatin calcium equivalent to 5 mg rosuvastatin and 10 mg ezetimibe.

ROSUZET 10 mg/10 mg: Each film-coated tablet contains rosuvastatin calcium equivalent to 10 mg rosuvastatin and 10 mg ezetimibe.

ROSUZET 20 mg/10 mg: Each film-coated tablet contains rosuvastatin calcium equivalent to 20 mg rosuvastatin and 10 mg ezetimibe.

ROSUZET 40 mg/10 mg: Each film-coated tablet contains rosuvastatin calcium equivalent to 40 mg rosuvastatin and 10 mg ezetimibe.

The other ingredients are:

Tablet Core

Lactose monohydrate, Croscarmellose Sodium, Povidone, Sodium Laurilsulfate, Cellulose, Microcrystalline 102, Hypromellose 2910, Silica Colloidal Anhydrous, Magnesium stearate.

Tablet Coating

ROSUZET 5 mg/10 mg - Opadry Yellow 02F220026 consisting of:

Hypromellose 2910 (E464), Titanium dioxide (E171), Iron oxide yellow (E172), Talc (E553b), Iron oxide red (E172), Macrogol 4000 (E1521).

ROSUZET 10 mg/10 mg - Opadry Beige 02F270003 consisting of:

Hypromellose 2910 (E464), Titanium dioxide (E171), Iron oxide yellow (E172), Macrogol4000 (E1521), Talc (E553b).

ROSUZET 20 mg/10 mg - VIVACOAT PC-2P-308 consisting of:

Hypromellose 6 (E464), Titanium dioxide (E171), Talc (E553b), Macrogol 4000 (E1521), Iron oxide yellow (E172).

ROSUZET 40 mg/10 mg - Opadry White OY-L-28900 consisting of:

Lactose monohydrate, Hypromellose 2910 (E464), Titanium dioxide (E171), Macrogol 4000 (E1521).

What ROSUZET looks like and contents of the pack

ROSUZET 5 mg/10 mg film-coated tablets: Light yellow, round, biconvex film-coated tablets with a diameter of 10 mm approximately and "EL 5" embossed on one side.

ROSUZET 10 mg/10 mg film-coated tablets: Beige, round, biconvex film coated tablets with a diameter of 10 mm approximately and "EL 4" embossed on one side.

ROSUZET 20 mg/10 mg film-coated tablets: Yellow, round, biconvex film coated tablets with a diameter of 10 mm approximately and "EL 3" embossed on one side.

ROSUZET 40 mg/10 mg film-coated tablets: White, round, biconvex film coated tablets with a diameter of 10 mm approximately and "EL 2" embossed on one side.

OPA/Al/PVC/Al blisters packed into carton boxes.

Pack size of 30-film-coated tablets.

Holder of Certificate of Registration

CIPLA MEDPRO (PTY) LTD.

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7530

Customer care: 080 222 6662

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ROSUZET 5 mg/10 mg – 55/7.5/0224

ROSUZET 10 mg/10 mg – 55/7.5/0225

ROSUZET 20 mg/10 mg – 55/7.5/0226

ROSUZET 40 mg/10 mg – 55/7.5/0227

Access to the corresponding Professional Information

To access corresponding Professional Information, scan the QR code below.

PLACE HOLDER:
The QR code to be generated and included after approval