PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

ROSUVASTATIN 5 CIPLA, 5 mg film-coated tablets

ROSUVASTATIN 10 CIPLA, 10 mg film-coated tablets

ROSUVASTATIN 20 CIPLA, 20 mg film-coated tablets

ROSUVASTATIN 40 CIPLA, 40 mg film-coated tablets

Rosuvastatin calcium

Contains sugar (lactose granules)

Contains Sunset Yellow (E110)

ROSUVASTATIN 5 CIPLA contains TARTRAZINE (E102)

Read all of this leaflet carefully before you start taking ROSUVASTATIN CIPLA:

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

ROSUVASTATIN CIPLA 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 CIPLA is used to reduce the risk of incidents that may cause damage to the heart muscle in patients at risk of developing heart disease because of build-up of fats in and on the blood vessels of the heart.

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

ROSUVASTATIN CIPLA 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 CIPLA 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 CIPLA or alternative therapy.
Specialist supervision is recommended when the 40 mg dose is initiated.

ROSUVASTATIN CIPLA 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 CIPLA

Do not take ROSUVASTATIN CIPLA:

- if you are hypersensitive (allergic) to rosuvastatin or any of the other ingredients of ROSUVASTATIN CIPLA (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 CIPLA**).
- 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 CIPLA (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 CIPLA

Tell your doctor or healthcare professional before taking ROSUVASTATIN CIPLA:

- 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.
- 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 CIPLA.**
- 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 CIPLA can lead to serious muscle problems (rhabdomyolysis), please see **Other medicine and ROSUVASTATIN CIPLA.**
- 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 CIPLA**).

ROSUVASTATIN CIPLA 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 CIPLA.

In a small number of people, ROSUVASTATIN CIPLA 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 CIPLA, 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 CIPLA.

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

Other medicines and ROSUVASTATIN CIPLA

Always tell your health care provider 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

ROSUVASTATIN CIPLA 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) may increase the effect of ROSUVASTATIN CIPLA and the risk of developing serious muscle problems (see **Do not take ROSUVASTATIN CIPLA** above).

Fusidic acid (an antibiotic) may increase the risk of developing serious muscle problems (see **Take special care with ROSUVASTATIN CIPLA** above). If you need to take oral fusidic acid to treat a bacterial infection you will need to temporarily stop using ROSUVASTATIN CIPLA. Your doctor will tell you when it is safe to restart ROSUVASTATIN CIPLA. Taking ROSUVASTATIN CIPLA 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 CIPLA** above), as these medicines may increase the effect of ROSUVASTATIN CIPLA and may lead to an increase in the possible side effects of ROSUVASTATIN CIPLA: ritonavir, lopinavir, atazanavir, ombitasvir, paritaprevir, dasabuvir, velpatasvir, grazoprevir, elbasvir, glecaprevir, pibrentasvir, darunavir, tipranavir.

Effect of ROSUVASTATIN CIPLA may be increased with

- warfarin, clopidogrel or ticagrelor (or any other medicine used for thinning the blood) as ROSUVASTATIN CIPLA may affect the way these medicines work; clopidogrel may increase the effect of ROSUVASTATIN CIPLA.
- regorafenib (used to treat cancer) as this may increase the effect of ROSUVASTATIN CIPLA.
- eltrombopag (used to treat low blood platelet counts caused by an autoimmune disorder) as this may increase the effect of ROSUVASTATIN CIPLA.
- dronedarone (used to treat abnormal heart rhythm) as this may increase the effect of ROSUVASTATIN CIPLA.
- itraconazole (used to treat fungal infections) as this may increase the effect of ROSUVASTATIN CIPLA.

Effect of ROSUVASTATIN CIPLA may be decreased with

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

ROSUVASTATIN CIPLA may increase the effect of other medicines

- oral contraceptives (the pill): ROSUVASTATIN CIPLA may increase the effect of contraceptives.
- hormone replacement therapy: ROSUVASTATIN CIPLA may increase the effect of these medicines.

Taking ROSUVASTATIN CIPLA with food and alcohol

You can take ROSUVASTATIN CIPLA 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 CIPLA.

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

ROSUVASTATIN CIPLA is contraindicated in pregnancy and lactation.

Driving and using machines

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

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

ROSUVASTATIN CIPLA contains lactose and Sunset Yellow

If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking ROSUVASTATIN CIPLA.

ROSUVASTATIN CIPLA contains a coating called Sunset Yellow, which may cause an allergic reaction.

ROSUVASTATIN 5 CIPLA contains tartrazine

ROSUVASTATIN 5 CIPLA contains tartrazine, which may cause an allergic reaction.

3. How to take ROSUVASTATIN CIPLA

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

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

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

The dosage range for ROSUVASTATIN CIPLA is 5 to 40 mg orally once a day. The recommended starting 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 CIPLA 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 starting 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 ROSUVASTATIN CIPLA 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 CIPLA 5 mg, doses above 10 mg should be carefully considered.

Race

A 5 mg starting dose of ROSUVASTATIN CIPLA should be considered for Asian patients.

Your doctor will tell you how long your treatment with ROSUVASTATIN CIPLA 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 CIPLA is started. Do not stop treatment early.

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

If you take more ROSUVASTATIN CIPLA 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 CIPLA

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

4. Possible side effects

ROSUVASTATIN CIPLA can have side effects.

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

If any of the following happens, stop taking ROSUVASTATIN CIPLA 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 ROSUVASTATIN CIPLA. 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)
- 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
- 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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website, or to Cipla Medpro (Pty) Ltd. by e-mail: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free). By reporting side effects, you can help provide more information on the safety of ROSUVASTATIN CIPLA.

5. How to store ROSUVASTATIN CIPLA

Store at or below 30 °C.

Protect from moisture.

Keep the blisters in the outer carton until required for use.

Store all medicines out of reach of children.

Do not use after the expiry date stated on the carton and blister.

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 ROSUVASTATIN CIPLA contains

The active substance is:

ROSUVASTATIN 5 CIPLA: each tablet contains 5 mg rosuvastatin as rosuvastatin calcium.

ROSUVASTATIN 10 CIPLA: each tablet contains 10 mg rosuvastatin as rosuvastatin calcium.

ROSUVASTATIN 20 CIPLA: each tablet contains 20 mg rosuvastatin as rosuvastatin calcium.

ROSUVASTATIN 40 CIPLA: each tablet contains 40 mg rosuvastatin as rosuvastatin calcium.

The other ingredients are: crospovidone, lactose granules, magnesium stearate, microcrystalline cellulose and sodium carbonate anhydrous.

Coating ingredients

ROSUVASTIN 5 CIPLA:

Opadry Yellow [containing FD&C Yellow #5/Tartrazine aluminium lake (E102), FD&C Yellow #6/Sunset Yellow FCF aluminium lake (E110), FD&C Blue #2/Indigo Carmine aluminium lake (E132), lecithin (soya) (E322), partially hydrolysed polyvinyl alcohol (E1203), talc (E553b), titanium dioxide (E171) and xanthan gum (E415)].

ROSUVASTIN 10 CIPLA, ROSUVASTIN 20 CIPLA, ROSUVASTIN 40 CIPLA:

Opadry pink [containing FD&C Red #40/Allura Red AC aluminium lake (E129), FD&C Yellow #6/Sunset Yellow FCF aluminium lake (E110), lecithin (soya) (E322), partially hydrolysed

polyvinyl alcohol (E1203), FD&C Blue #2/Indigo Carmine aluminium lake (E132), talc (E553b), titanium dioxide (E171) and xanthan gum (E415)].

What ROSUVASTATIN CIPLA looks like and contents of the pack

ROSUVASTATIN 5 CIPLA: yellow-coloured, round, biconvex, film-coated tablets, with "5" debossed on one side.
Carton containing 30 tablets packed in PVC/PVDC aluminium foil blister strips of 15 tablets each.

ROSUVASTATIN 10 CIPLA: pink-coloured, round, biconvex, film-coated tablets, with "10" debossed on one side.
Carton containing 30 tablets packed in PVC/PVDC aluminium foil blister strips of 15 tablets each.

ROSUVASTATIN 20 CIPLA: pink-coloured, round, biconvex, film-coated tablets, with "20" debossed on one side.
Carton containing 30 tablets packed in PVC/PVDC aluminium foil blister strips of 15 tablets each.

ROSUVASTATIN 40 CIPLA: pink-coloured, oval, biconvex, film-coated tablets, with "40" debossed on one side.
Carton containing 30 tablets packed in PVC/PVDC aluminium foil blister strips of 15 tablets each.

Holder of certificate of registration

CIPLA MEDPRO (PTY) LTD.

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ROSUVASTATIN 20 CIPLA: 48/7.5/0190

ROSUVASTATIN 40 CIPLA: 48/7.5/0191

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.