

Applicant/PHRC: **Hetero Drugs South Africa (Pty) Ltd**

Product proprietary name: **ROSUTERO**

Dosage form and strength: **Tablet, each film coated tablet contains rosuvastatin 5 mg, 10 mg, 20 mg & 40 mg**

PATIENT INFORMATION LEAFLET FOR ROSUTERO

SCHEDULING STATUS

S4

ROSUTERO 5 mg (film-coated tablet)

ROSUTERO 10 mg (film-coated tablet)

ROSUTERO 20 mg (film-coated tablet)

ROSUTERO 40 mg (film-coated tablet)

ROSUTERO contains rosuvastatin

ROSUTERO contains sugar: lactose monohydrate

ROSUTERO 5 mg: contains 31,300 mg lactose monohydrate.

ROSUTERO 10 mg: contains 62,600 mg lactose monohydrate.

ROSUTERO 20 mg: contains 125,200 mg lactose monohydrate.

ROSUTERO 40 mg: contains 250,400 mg lactose monohydrate

Read all of this leaflet carefully before you start taking ROSUTERO

- 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.
- ROSUTERO 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 ROSUTERO is and what it is used for
2. What you need to know before you take ROSUTERO
3. How to take ROSUTERO
4. Possible side effects

Applicant/PHRC: **Hetero Drugs South Africa (Pty) Ltd**

Product proprietary name: **ROSUTERO**

Dosage form and strength: **Tablet, each film coated tablet contains rosuvastatin 5 mg, 10 mg, 20 mg & 40 mg**

5. How to store ROSUTERO

6. Contents of the pack and other information

1. What ROSUTERO is and what it is used for

ROSUTERO contains 5 mg, 10 mg, 20 mg or 40 mg of rosuvastatin, as rosuvastatin calcium, and belongs to a group called HMG-CoA reductase inhibitors.

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

ROSUTERO 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.

ROSUTERO 40 mg 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 ROSUTERO or alternative therapy.

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

2. What you need to know before you take ROSUTERO

Do not take ROSUTERO:

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

Applicant/PHRC: **Hetero Drugs South Africa (Pty) Ltd**

Product proprietary name: **ROSUTERO**

Dosage form and strength: **Tablet, each film coated tablet contains rosuvastatin 5 mg, 10 mg, 20 mg & 40 mg**

- if you take a medicine called ciclosporin (used, for example, after organ transplants) (see Other Medicines and ROSUTERO)
- 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 myopathy or any disease of the muscle.
- Children as safety and efficacy have not been demonstrated.

Warnings and precautions

Take special care with ROSUTERO:

Tell your doctor or health care provider if:

- you have high blood sugar or raised HbA1c (a measure of blood sugar).
- you have ever been told that you have problems with your liver or kidneys.
- you have any unexplained aches or pains in your muscles or have a history of muscle pain.
- you regularly drink large amounts of alcohol.
- you have an underactive thyroid gland.
- you are taking protease inhibitors (used to fight the HIV infection).
- you have severe respiratory failure.

When taking your tablets, tell your doctor, pharmacist or other health care professional if you have any unexplained aches or pains in your muscles.

If you become seriously ill or you go into hospital, let the medical staff looking after you know that you are taking ROSUTERO, as it may be better for you to stop taking it for a short time.

Other medicines and ROSUTERO

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

Applicant/PHRC: **Hetero Drugs South Africa (Pty) Ltd**

Product proprietary name: **ROSUTERO**

Dosage form and strength: **Tablet, each film coated tablet contains rosuvastatin 5 mg, 10 mg, 20 mg & 40 mg**

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

- ciclosporin (used for example, after an organ transplant)
- warfarin or clopidogrel (or any other medicine used for thinning your blood)
- gemfibrozil or fenofibrate (fibric acid medicine used to lower the fat in your blood)
- niacin and nicotinic acid (used for example, to lower the fat in your blood)
- antacids (medicines used to treat heartburn)
- erythromycin (an antibiotic), fusidic acid (an antibiotic – please see below and Warnings and precautions)
- regorafenib (used to treat cancer)
- darolutamide (used to treat cancer)

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 ROSUTERO can lead to serious muscle problems (rhabdomyolysis).

If you are taking antiviral medications alone or in combination such as lopinavir, ritonavir, sofosbuvir, velpatasvir, voxilaprevir, grazoprevir, elbasvir, ombitasvir, paritaprevir, dasabuvir, glecaprevir, pibrentasvir - (used to fight infections, including the HIV infection), regorafenib and darolutamide (used to treat cancer).

ROSUTERO with food and drink

ROSUTERO may be taken with or without food.

Pregnancy and breastfeeding

Do not take ROSUTERO if you are pregnant or breastfeeding.

If you become pregnant while taking ROSUTERO stop taking it immediately and tell your doctor.

Women should avoid becoming pregnant while taking ROSUTERO by using suitable contraception.

*Applicant/PHRC: **Hetero Drugs South Africa (Pty) Ltd***

*Product proprietary name: **ROSUTERO***

*Dosage form and strength: **Tablet, each film coated tablet contains rosuvastatin 5 mg, 10 mg, 20 mg & 40 mg***

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.

Driving and using machines

ROSUTERO may cause dizziness, therefore patients taking ROSUTERO should not drive or use machines until their individual susceptibility to dizziness is known.

Important information about some of the ingredients of ROSUTERO

ROSUTERO contains lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking ROSUTERO.

3 How to take ROSUTERO

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

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

Treatment with ROSUTERO is usually started with one 5 mg tablet taken once daily. Some people may be asked to start treatment with either a 10 mg or a 20 mg tablet taken once daily.

People of Asian origin should start treatment with one 5 mg tablet taken once a day. The 40 mg dose is contraindicated in these patients.

After checking the amount of fats in your blood, your doctor may decide to increase your dose until you are taking the amount of ROSUTERO that is right for you. In adults the maximum daily dose is 40 mg. In children 10 years of age and above, the maximum daily dose is 20 mg.

Your doctor will tell you how long your treatment with ROSUTERO will last. Do not stop taking your

*Applicant/PHRC: **Hetero Drugs South Africa (Pty) Ltd***

*Product proprietary name: **ROSUTERO***

*Dosage form and strength: **Tablet, each film coated tablet contains rosuvastatin 5 mg, 10 mg, 20 mg & 40 mg***

tablets even if you are feeling well, unless your doctor tells you to or unless you become pregnant.

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

If you take more ROSUTERO 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 ROSUTERO

Skip the missed dose and go back to your regular schedule. Do not take a double dose to make up for a forgotten dose.

4. Possible side effects

ROSUTERO can have side effects.

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

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

- you have 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 (Stevens-Johnson syndrome).
- yellowing of the skin and eyes, also called jaundice.

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

Applicant/PHRC: **Hetero Drugs South Africa (Pty) Ltd**

Product proprietary name: **ROSUTERO**

Dosage form and strength: **Tablet, each film coated tablet contains rosuvastatin 5 mg, 10 mg, 20 mg & 40 mg**

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

- you have any unusual aches or pains in your muscles which go on for longer than you might expect, especially if you develop a fever or feel unwell. These have 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).
- severe stomach pain due to inflamed pancreas (pancreatitis).
- 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:

- headache,
- dizziness,
- stomach pain,
- constipation,
- feeling sick (nausea),
- muscle pain,
- feeling weak (asthenia),
- increased blood glucose levels, diabetes.

Less frequent side effects:

- abnormal bleeding or bruising,
- rash, itching or other skin reactions,
- memory loss or impairment, forgetfulness and confusion,

Applicant/PHRC: **Hetero Drugs South Africa (Pty) Ltd**

Product proprietary name: **ROSUTERO**

Dosage form and strength: **Tablet, each film coated tablet contains rosuvastatin 5 mg, 10 mg, 20 mg & 40 mg**

- numbness, tingling, loss of sensation in the arms and legs, burning feeling in the hands or feet (polyneuropathy),
- 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,
- severe stomach pain (inflamed pancreas),
- jaundice (yellowing of the skin and eyes),
- hepatitis (an inflamed liver),
- increased liver enzymes in the blood,
- joint pain,
- traces of blood in your urine,
- breast enlargement in men (gynaecomastia).

Unknown frequency:

- depression,
- diarrhoea,
- 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 SAHPRA website or to the Holder of certificate of registration through the mail: pvg.cdma@heterogroups.com.

By reporting side effects, you can help provide more information on the safety of ROSUTERO.

Applicant/PHRC: **Hetero Drugs South Africa (Pty) Ltd**

Product proprietary name: **ROSUTERO**

Dosage form and strength: **Tablet, each film coated tablet contains rosuvastatin 5 mg, 10 mg, 20 mg & 40 mg**

5. How to store ROSUTERO

Store at or below 25 °C.

Store in the original package.

Protect from light / moisture.

KEEP OUT OF REACH OF CHILDREN.

6. Contents of the pack and other information

What ROSUTERO contains

The active substance is rosuvastatin.

The other ingredients are:

Lactose monohydrate, cellulose, microcrystalline (PH 102), crospovidone, hydroxypropyl cellulose, sodium hydrogen carbonate, talc, magnesium stearate.

Coating

Opadry II yellow, opadry II pink, titanium dioxide.

What ROSUTERO looks like and contents of the pack

ROSUTERO 5 mg

Light yellow to yellow, round, bevel-edged biconvex film-coated tablets debossed with 'H' on one side and 'R3' on the other side.

ROSUTERO 10 mg

Light pink to pink, round, bevel-edged biconvex film-coated tablets debossed with 'H' on one side and 'R4' on the other side.

ROSUTERO 20 mg

Light pink to pink, round, bevel-edged biconvex film-coated tablets debossed with 'H' on one side and 'R5' on the other side.

Applicant/PHRC: **Hetero Drugs South Africa (Pty) Ltd**

Product proprietary name: **ROSUTERO**

Dosage form and strength: **Tablet, each film coated tablet contains rosuvastatin 5 mg, 10 mg, 20 mg & 40 mg**

ROSUTERO 40 mg

Light pink to pink, oval, bevel-edged biconvex film-coated tablets debossed with 'H' on one side and 'R6' on the other side.

ROSUTERO 5 mg, 10 mg, 20 and 40 mg

10's – Alu-Alu blister pack

10 tablets packed in PVC aluminium blister pack.

ROSUTERO 5 mg, 10 mg, 20 and 40 mg

1000's LDPE Bag

Low density polyethylene bag, with plain triple laminated bag with silica gel canister 5 g.

Holder of Certificate of Registration

Hetero Drugs South Africa (Pty) Ltd

Waterfall Corporate Campus,

Building No.2, First Floor,

74 Waterfall Drive,

Midrand, 2066

Telephone number: 012 644 1220

e-mail address: nokuthula.n@hetero.com

This leaflet was last revised in

17 June 2026

Registration numbers:

ROSUTERO 5: 59/7.5/0673

ROSUTERO 10: 59/7.5/0674

*Applicant/PHRC: **Hetero Drugs South Africa (Pty) Ltd***

*Product proprietary name: **ROSUTERO***

*Dosage form and strength: **Tablet, each film coated tablet contains rosuvastatin 5 mg, 10 mg, 20 mg & 40 mg***

ROSUTERO 20: 59/7.5/0675

ROSUTERO 40: 59/7.5/0676

Access to the corresponding Professional Information

Hetero Drugs South Africa (Pty) Ltd

Waterfall Corporate Campus,

Building No.2, First Floor,

74 Waterfall Drive,

Midrand, 2066

Telephone number: 012 644 1220

e-mail address: nokuthula.n@hetero.com