

Scheduling Status:**S4****COLEROS 5, 5 mg film-coated tablets****COLEROS 10, 10 mg film-coated tablets****COLEROS 20, 20 mg film-coated tablets****COLEROS 40, 40 mg film-coated tablet****Rosuvastatin calcium**

Contains sugar (COLEROS 5: 20,775 mg, COLEROS 10: 41,550 mg, COLEROS 20: 83,100 mg and COLEROS 40: 166,200 mg lactose monohydrate)

Read all of this leaflet carefully before you start taking COLEROS:

- 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.
- COLEROS 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 COLEROS is and what it is used for
2. What you need to know before you take COLEROS
3. How to take COLEROS
4. Possible side effects
5. How to store COLEROS
6. Contents of the pack and other information

1. What COLEROS is and what it is used for

COLEROS contains rosuvastatin calcium equivalent to 5 mg, 10 mg, 20 mg or 40 mg rosuvastatin per film-coated tablet and belongs to a group of medicines called statins.

COLEROS is used to reduce your risk of incidents that may cause damage to your heart muscle if you are at risk of developing heart disease as a result of build-up of fats in and on the blood vessels of your heart. COLEROS is used to reduce your risk of non-fatal stroke, non-fatal heart attack, and the need for procedures such as bypass surgery for heart disease.

COLEROS is used, together with diet (when diet and exercise is inadequate), to lower the amount of cholesterol (a fat-like substance) and other fatty substances your blood.

COLEROS 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.

COLEROS 40 mg will only be considered in patients with severe high cholesterol and high risk of heart disease, who do not achieve their treatment goal on 20 mg of COLEROS or alternative therapy.

A specialist will supervise your treatment when the 40 mg dose is initiated.

COLEROS can be used in children and adolescents (10 to 17 years of age) to reduce the total cholesterol, “bad” cholesterol (LDL) and other lipids in patients with genetically inherited high cholesterol called heterozygous familial hypercholesterolaemia (HeFH).

2. What you need to know before you take COLEROS

Do not take COLEROS:

- if you are hypersensitive (allergic) to rosuvastatin or any of the other ingredients of COLEROS (as listed in section 6)
- if you currently have a liver disease
- if you have severe kidney problems
- if you have been diagnosed with myopathy (a muscle disease)
- if you take a medicine called ciclosporin (used, for example, after organ transplants)
- if you are pregnant or breastfeeding or if you are a woman of childbearing potential not using appropriate contraceptive measures.

In addition, do not take COLEROS 40 (the highest dose) if you are at risk of muscle disorders. 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 (used for lowering high cholesterol levels)
- if you are of Asian descent.

Warnings and precautions

Take special care with COLEROS:

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

COLEROS 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 COLEROS.

COLEROS 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 COLEROS, 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 COLEROS.

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

You may be at risk of 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).

Other medicines and COLEROS

Always tell your health care 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 medicines:

COLEROS should not be used together with ciclosporin (used for example, after organ transplants).

The 40 mg dose should not be taken together with 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 COLEROS and the risk of developing serious muscle problems (see Do not take COLEROS above).

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

Effect of COLEROS may be increased by use with:

- clopidogrel
- regorafenib (used to treat cancer)
- eltrombopag (used to treat low blood platelet counts caused by an autoimmune disorder)
- dronedarone (used to treat abnormal heart rhythm)
- itraconazole (used to treat fungal infections)

Effect of COLEROS may be decreased by:

- indigestion remedies, such as antacids (used to neutralise acid in your stomach)
- erythromycin (an antibiotic)

Other medicines:

- warfarin (or any other medicine used for thinning the blood) as COLEROS may affect the way this medicine works

- oral contraceptives (the pill) as COLEROS may increase the effect of contraceptives
- hormone replacement therapy as COLEROS may increase the effect of these medicines.

Taking COLEROS with food and alcohol

You can take COLEROS 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 this medicine.

Women of childbearing potential should use appropriate contraceptive measures.

You should not take COLEROS during pregnancy and breastfeeding.

Driving and using machines

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

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

COLEROS contains lactose monohydrate

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

3. How to take COLEROS

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

Always take COLEROS 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 COLEROS 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 COLEROS-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.

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

A 5 mg starting dose is recommended for patients of Asian ancestry.

Children and adolescents 10 - 17 years of age

In children and adolescents with heterozygous familial hypercholesterolaemia the usual dose range is 5 - 20 mg orally once daily.

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

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

If you take more COLEROS 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 COLEROS

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

4. Possible side effects

COLEROS can have side effects.

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

If any of the following happens, stop taking COLEROS 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 reaction to COLEROS. 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)
- sleep disturbances (including insomnia and nightmares),
- myasthenia gravis (a disease causing general muscle weakness including in some cases muscles used when breathing),
- ocular myasthenia (a disease causing eye muscle weakness).

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 COLEROS

Store all medicines out of reach of children.

Store at or below 25 °C.

Store in the original container.

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 COLEROS contains

COLEROS 5: Each film-coated tablet contains rosuvastatin calcium equivalent to 5 mg rosuvastatin.

COLEROS 10: Each film-coated tablet contains rosuvastatin calcium equivalent to 10 mg rosuvastatin.

COLEROS 20: Each film-coated tablet contains rosuvastatin calcium equivalent to 20 mg rosuvastatin.

COLEROS 40: Each film-coated tablet contains rosuvastatin calcium equivalent to 40 mg rosuvastatin.

The other ingredients of the tablet core are lactose monohydrate, sodium hydrogen carbonate, cellulose microcrystalline, crospovidone and magnesium stearate.

The other ingredients of the tablet coating, Opadry II pink 32K540023, are hypromellose (15 mPas), lactose monohydrate, titanium dioxide, triacetin, iron oxide red.

What COLEROS looks like and contents of the pack

COLEROS 5: Pink, 4,50 mm, round, biconvex, bevelled edge, film-coated tablet, debossed with 'R5' on one side and plain on other side.

COLEROS 10: Pink, 5,50 mm, round, biconvex, bevelled edge, film-coated tablet, debossed with 'R10' on one side and plain on other side.

COLEROS 20: Pink, 7,00 mm, round, biconvex, film-coated tablet, debossed with 'R20' on one side and plain on other side.

COLEROS 40: Pink, 11,50 mm x 6,90 mm, oval, biconvex, film-coated tablet, debossed with 'R40' on one side and plain on other side.

COLEROS film-coated tablets are packed in:

OPA/Al/PVC-Aluminium blisters strips in an outer carton. 10 Tablets are packed per blister and three blisters are packed in an outer carton. Pack size: 30's.

Holder of Certificate of Registration:

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