1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

REGUCHOLE 10/5 mg tablets

Ezetimibe, Rosuvastatin

Contains sugar: Lactose monohydrate 228,29 mg

REGUCHOLE 10/10 mg tablets

Ezetimibe, Rosuvastatin

Contains sugar: Lactose monohydrate 238,69 mg

REGUCHOLE 10/20 mg tablets

Ezetimibe, Rosuvastatin

Contains sugar: Lactose monohydrate 243,89 mg

Read all of this leaflet carefully before you start taking REGUCHOLE

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- REGUCHOLE 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 REGUCHOLE is and what it is used for
2. What you need to know before you take REGUCHOLE

3. How to take REGUCHOLE
4. Possible side effects
5. How to store REGUCHOLE
6. Contents of the pack and other information

1. What REGUCHOLE is and what it is used for

REGUCHOLE contains the active medicines ezetimibe and rosuvastatin.

REGUCHOLE helps to lower cholesterol levels. It is used in people whose cholesterol levels are too high and when diet alone cannot lower these levels adequately.

What is high cholesterol

Cholesterol is one of several fatty substances found in the bloodstream. Your total cholesterol is made up mainly of low density lipoprotein (LDL) and high density lipoprotein (HDL) cholesterol.

LDL cholesterol is often called "bad" cholesterol because it can build up in the walls of your arteries forming plaque. Eventually this plaque build-up can lead to a narrowing of the arteries. This narrowing can slow or block blood flow to vital organs such as the heart and brain. This blocking of blood flow can result in a heart attack or stroke.

HDL cholesterol is often called "good" cholesterol because it helps keep the bad cholesterol from building up in the arteries and protects against heart disease.

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.

2. What you need to know before you take REGUCHOLE

Do not take REGUCHOLE:

- If you are hypersensitive (allergic) to ezetimibe, rosuvastatin or any of the other ingredients of REGUCHOLE (listed in section 6).
- If you are pregnant or intend to become pregnant. If you are a woman of childbearing age and are taking REGUCHOLE, use a proven method of birth control to avoid pregnancy. The medicine may affect your developing baby if you take it during pregnancy (see Pregnancy, breastfeeding and fertility).
- If you are breastfeeding. REGUCHOLE may pass into breast milk and affect your baby (see Pregnancy, breastfeeding and fertility).
- If you have liver conditions or active liver disease.
- If you have severe kidney disease.
- If you are taking a medicine to suppress your immune system, called ciclosporin (see Other medicines and REGUCHOLE).
- If you have a previous history of muscular problems (myopathy) from using other medicines used to treat high cholesterol.
- If you have gall bladder disease and you are taking another medicine to lower cholesterol levels, called fenofibrate (see Other medicines and REGUCHOLE).
- If you are taking an antibiotic medicine to treat infection, called fusidic acid (see Other medicines and REGUCHOLE).

REGUCHOLE is not recommended for use in children (see Warnings and precautions).

Warnings and precautions

Take special care with REGUCHOLE:

- If you have a history of heavy alcohol consumption. Your doctor may ask you to have your liver function tested before you start to take REGUCHOLE.

- If you have a history of liver problems. Your doctor may ask you to have your liver function tested before you start to take REGUCHOLE.
- If you are elderly, as you may be at risk to develop muscle weakness (myopathy).
- If you have low thyroid hormone levels (hypothyroidism), as you may be at risk to develop muscle weakness (myopathy).
- If you have kidney impairment, as you may be at risk to develop muscle weakness (myopathy).
- If you notice any muscle pain, muscle tenderness or muscle weakness, with or without fever and discomfort, you must immediately tell your doctor.
- If you have a previous history of muscular problems from using other medicines used to treat high cholesterol.
- If you have been diagnosed with high blood glucose levels.
- If you have been diagnosed with heart problems.
- If you have been diagnosed with diabetes mellitus.
- If you have short breath, difficulty breathing, cough and worsening of your health, tell your doctor. You may have a lung condition called interstitial lung disease.
- If you notice any disturbances in your sleep, as REGUCHOLE may affect your sleep.
- If you are an Asian patient, your doctor will adjust your dosage accordingly.
- If you have kidney problems.

Children and adolescents

There is no experience with REGUCHOLE in children, therefore treatment with REGUCHOLE is contraindicated (see Do not take REGUCHOLE).

Other medicines and REGUCHOLE

Always tell your healthcare 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:

- Ciclosporin: medicine used to suppress the immune system (see Do not take REGUCHOLE).
- Fenofibrate: medicine to lower triglyceride levels, if you have gall bladder disease (see Do not take REGUCHOLE).
- Fusidic acid: antibiotic used to treat infection (see Do not take REGUCHOLE).
- Antacids: medicines used to treat reflux or ulcers. REGUCHOLE should be taken 2 hours before or 2 hours after taking an antacid.
- Bile acid sequestrants (e.g. cholestyramine): medicines used to lower cholesterol levels.
- Fibrates: other medicines to lower cholesterol levels.
- Other cholesterol-lowering medicines (e.g. gemfibrozil, fibrates): medicines used to lower cholesterol levels.
- Anticoagulants (e.g. warfarin): medicine used to prevent blood clots.
- HIV protease inhibitors: medicines used to treat HIV infection.
- Hepatitis C antivirals (e.g. elbasvir, grazoprevir): medicines used to treat the hepatitis C virus infection.
- Colchicine: medicine used to treat gout.
- Daptomycin: medicine used to treat complicated skin and skin structure infections and bacteraemia.
- Ticagrelor: medicine used to prevent blood clots from forming in your blood.

REGUCHOLE with food

REGUCHOLE may be given at any time of the day, with or without food.

Pregnancy, breastfeeding and fertility

You should not take REGUCHOLE if you are pregnant or breastfeeding your baby.

If you are a woman of childbearing age and are taking REGUCHOLE, use a proven method of birth control to avoid pregnancy.

REGUCHOLE may affect your developing baby if you take it during pregnancy.

If you become pregnant while you are taking REGUCHOLE, stop taking it and tell your doctor immediately.

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 healthcare provider for advice before taking this medicine.

Driving and using machines

There have been side effects such as dizziness reported with REGUCHOLE that may affect your ability to drive or operate machinery.

It is not always possible to predict to what extent REGUCHOLE 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 REGUCHOLE affects them (see section 4).

REGUCHOLE contains lactose

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

3. How to take REGUCHOLE

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

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

Once you have been controlled on the individual medicines within REGUCHOLE as separate medicines, then your doctor will prescribe REGUCHOLE.

In adults the usual dose of REGUCHOLE is one tablet per day.

Cholesterol-lowering medicines are used together with lifestyle changes to help lower cholesterol.

Your doctor will tell you how long your treatment with REGUCHOLE will last. If you have the impression that the effect of REGUCHOLE is too strong or too weak, tell your doctor or pharmacist.

If you take more REGUCHOLE 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 REGUCHOLE

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

If you have missed a dose of REGUCHOLE, take the dose that you have missed as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose. If you have forgotten to take several doses, contact your doctor without delay.

4. Possible side effects

REGUCHOLE can have side effects.

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

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

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

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

- an elevation in blood glucose levels, a significant increase in your need to urinate or if you are significantly more hungry or thirsty than usual, as these may be signs of diabetes mellitus,
- sudden pain in the upper abdomen, nausea and vomiting or an abnormally fast heart rate, as these may be signs of inflammation of the pancreas (pancreatitis),

- muscle weakness, feeling abnormally tired, body aches, cramping, dark-coloured urine or fever, as these may be signs of muscle breakdown (myopathy or rhabdomyolysis),
- chest pain,
- blood disorders which are usually detected in blood tests but may be seen as bruising or prolonged bleeding after injury, small red spots on the skin or abnormal tiredness (thrombocytopaenia),
- swelling of the liver, including yellowing of your skin and eyes (jaundice), sometimes with fever, pale stools and dark urine (hepatitis or hepatic failure),
- pain in the back or upper abdomen, heartburn, nausea or vomiting, as these may be signs of gallstones (cholelithiasis) or swelling of the gall bladder (cholecystitis).

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:

- viral infection, sore throat (pharyngitis), runny nose or sinus congestion (sinusitis),
- headache, dizziness,
- abdominal pain, nausea, loose stools (diarrhoea), difficulty passing stools (constipation), passing wind (flatulence),
- elevation in some laboratory blood tests of liver,
- muscle pain (myalgia), joint pain (arthralgia),
- tiredness (fatigue).

Less frequent side effects:

- decreased appetite,
- abnormal dreaming, nightmares, sleepwalking,

- hot flush, high blood pressure (hypertension),
- cough,
- burning sensation, bloating or gassiness, nausea or feeling full too quickly after starting to eat (dyspepsia, gastro-oesophageal reflux disease),
- back pain, pain in different parts of the body, muscle spasms, neck pain,
- abnormal physical weakness or lack of energy (asthenia), swelling due to build-up of fluid (oedema),
- elevation in some laboratory blood tests of liver,
- depression,
- paraesthesia,
- memory loss,
- asthenia.

Side effects with an unknown frequency:

- sleep disorders, inability to sleep (insomnia), nightmares,
- breast tissue swelling in males (gynaecomastia).

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: https://www.sahpra.org.za/health-products-vigilance/

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

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

5. How to store REGUCHOLE

Store all medicines out of reach of children.

Store at or below 30 °C.

Keep in original packaging until required for use.

Do not store in a bathroom.

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).

6. Contents of the pack and other information

What REGUCHOLE contains

The active substances in REGUCHOLE 10/5 mg are 10 mg of ezetimibe and rosuvastatin calcium equivalent to 5 mg of rosuvastatin.

The active substances in REGUCHOLE 10/10 mg are 10 mg of ezetimibe and rosuvastatin calcium equivalent to 10 mg of rosuvastatin.

The active substances in REGUCHOLE 10/20 mg are 10 mg of ezetimibe and rosuvastatin calcium equivalent to 20 mg of rosuvastatin.

The other ingredients are croscarmellose sodium, crospovidone type A, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone K-30 and sodium laurilsulfate.

REGUCHOLE 10/5 mg tablets:

Contains sugar: Lactose monohydrate 228,29 mg

REGUCHOLE 10/10 mg tablets:

Contains sugar: Lactose monohydrate 238,69 mg

REGUCHOLE 10/20 mg tablets:

Contains sugar: Lactose monohydrate 243,89 mg

What REGUCHOLE looks like and contents of the pack

REGUCHOLE 10/5: White to off-white, round, flat, uncoated tablet, engraved E2 on one side and 2 on the other side. The diameter of the tablet is 10 mm.

REGUCHOLE 10/10 mg: White to off-white, oval, biconvex, uncoated tablet, engraved E1 on one side and 1 on the other side. The dimensions of the tablet are 15 mm x 7 mm.

REGUCHOLE 10/20 mg: White to off-white, round, biconvex, uncoated tablet. The diameter of the tablet is 11 mm.

Tablets are packed in blisters consisting of Polyamide-Aluminium-Polyvinylchloride laminate and aluminium lidding foil with ten tablets per blister strip. The blisters are packed into carton boxes containing 30 tablets per pack.

Holder of Certificate of Registration

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Hotline: 0800 122 912

This leaflet was last revised in

08 November 2022

Registration number

REGUCHOLE 10/5 mg: 54/7.5/0693

REGUCHOLE 10/10 mg: 54/7.5/0694

REGUCHOLE 10/20 mg: 54/7.5/0695

Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

https://www.sahpra.org.za/pi-pil-repository/

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

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