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WHAT IS ROSUVASTATIN SANDOZ USED FOR

You have been prescribed Rosuvastatin Sandoz because either:

(a) You have a high cholesterol level. This means you are at risk of getting a heart attack or stroke. You have been advised to take a statin, because changing your diet and taking more exercise were not enough to correct your cholesterol levels. You should continue with your cholesterol-lowering diet and exercise while you are taking Rosuvastatin Sandoz.

Or

(b) You have other factors that increase your risk of getting a heart attack, stroke or related health problems. Heart attack, stroke and other problems can be caused by a disease called atherosclerosis. Atherosclerosis is due to build-up of fatty deposits in your arteries.

HOW ROSUVASTATIN SANDOZ WORKS

Rosuvastatin Sandoz belongs to a group of medicines called statins. There are different types of cholesterol found in the blood, including – ‘bad’ cholesterol (LDL-C) and ‘good’ cholesterol (HDL-C).

- Rosuvastatin Sandoz can reduce the ‘bad’ cholesterol and increase the ‘good’ cholesterol.
- It works by helping to block your body’s production of ‘bad’ cholesterol in the liver. It also improves your body’s ability to remove it from your blood.

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 getting a heart attack, a stroke or related health problems.

BEFORE YOU USE ROSUVASTATIN SANDOZ**- When you must not use it**

- If you are allergic (hypersensitive) to rosuvastatin, or to any of the ingredients.
- If you have liver disease.
- If you have severe kidney problems.
- If you have repeated or unexplained muscle aches or pains.
- If you take a drug called ciclosporin.
- If you are pregnant or breast-feeding. If you become pregnant while taking Rosuvastatin Sandoz, stop taking it immediately and tell your doctor. Women should avoid becoming pregnant while taking this medicine by using suitable contraception.

If you think any of the above situations applies to you do not take the tablets. Consult your doctor and take his/her advice.

In addition, do not take the dose of rosuvastatin 40 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.
- 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.

- In situations where increase in plasma levels may occur.
- If you are of Asian origin.
- If you take other medicines called fibrates to lower your cholesterol.

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

Pregnancy and breast-feeding

Do not take Rosuvastatin Sandoz if you are pregnant or breast-feeding. If you become pregnant while taking Rosuvastatin Sandoz stop taking it immediately and tell your doctor.

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

Ask your doctor or pharmacist for advice before taking any medicine

- Before you start use it

You should check with your doctor before taking Rosuvastatin Sandoz:

- If you have problems with your kidneys.
- If you have had 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. Tell your doctor immediately if you have unexplained muscle aches or pains especially if you feel unwell or have a fever.
- If you have problems with your liver.
- If you regularly drink large amounts of alcohol.
- If you are of Asian origin.
- If you take medicines used to fight the HIV infection (e.g. lopinavir/ritonavir).
- If you have severe respiratory failure.
- If you are over 70 years old.
- If your thyroid gland is not working properly.
- If you take other medicines called fibrates to lower your cholesterol.
- If you have diabetes.

Talk to your doctor or pharmacist before taking Rosuvastatin Sandoz:

- If you have or have had myasthenia (a disease with general muscle weakness including in some cases muscles used when breathing), or ocular myasthenia (a disease causing eye muscle weakness) as statins may sometimes aggravate the condition.

- Taking other medicines

Tell your doctor or pharmacist if you are taking, or have recently taken, any other medicines including any you bought without a prescription.

Tell your doctor if you are taking any of the following:

- Ciclosporin (used for example, after organ transplants)
- Lopinavir/ritonavir (used to fight the HIV infection)
- fibrates (such as gemfibrozil, fenofibrate) or any other medicine used to lower cholesterol (such as ezetimibe)
- antacids
- erythromycin (an antibiotic)
- warfarin (or any other drug used for thinning the blood)
- oral contraceptive
- hormone replacement therapy

The effects of these medicines could be changed by Rosuvastatin Sandoz or they could change the effects of Rosuvastatin Sandoz.

Ask your doctor if you are not sure what these medicines are.

HOW TO USE ROSUVASTATIN SANDOZ

- How much to use

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

Usual doses in adults

The usual recommended starting dose of Rosuvastatin Sandoz is 10 mg once daily. However, a starting dose of 5 mg once daily would be considered for certain groups of patients or patients requiring less aggressive cholesterol reductions.

Your doctor will choose your starting dose depending upon:

- Your cholesterol level.
- Your risk of suffering a heart attack or stroke.
- Whether you have factors that may make you more sensitive to possible side effects.

- When to use it

Always take this medicine exactly as your doctor told you. Please ask your doctor or pharmacist if you are not sure.

- How long to use it

It is important to take your medicine every day. Always consult your doctor, if you wish to stop taking this medicine. Even if you feel well, it may be necessary to continue taking this medicine.

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

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the nearest emergency department if you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

WHILE YOU ARE USING IT

- Things you must do

- Take your medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists treating you that you are taking Rosuvastatin Sandoz.
- Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

- Do not stop taking the medicine unless advised by your doctor.

- Do not take any new medicines without consulting your doctor.
- Do not give Rosuvastatin Sandoz to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines
Most people can drive a car and operate machinery while using Rosuvastatin Sandoz – it will not affect their ability. However, some people feel dizzy during treatment with Rosuvastatin Sandoz. If you feel dizzy, consult your doctor before attempting to drive or use machines.

SIDE EFFECTS

Like all medicines, Rosuvastatin Sandoz can cause side effects, although not everybody gets them. They are usually mild and disappear after a short time.

A list of possible side effects is given below.

Very common: affects more than 1 in 10 patients

Common: affects more than 1 in 10 but less than 1 in 100 patients

Uncommon: affects more than 1 in 100 but less than 1 in 1000 patients

Rare: affects more than 1 in 1,000 but less than 1 in 10,000 patients

Very rare: affects less than 1 in 10,000 patients

Not known: cannot be estimated from the available data.

Blood and lymphatic system disorders

Rare: low platelet levels

Immune system disorders

Rare: hypersensitivity reactions including angioedema (severe swelling of the mucous membrane)

Endocrine disorders

Common: diabetes mellitus

Psychiatric disorders

Not known: depression

Nervous system disorders

Common: headache, dizziness

Very rare: nerve damage, memory loss

Not known: damage to peripheral nerves, sleep disturbances (including insomnia and nightmares),

myasthenia gravis (a disease causing general muscle weakness including in some cases muscle used when breathing)

Eye disorders

Not known: Ocular myasthenia (a disease causing eye muscle weakness)

Talk to your doctor if you experience weakness in your arms or legs that worsens after periods of activity, double vision or drooping of your eyelids, difficulty swallowing or shortness of breath.

Respiratory system disorders

Not known: cough, breathing problem

Gastrointestinal disorders

Common: constipation, nausea, abdominal pain
Rare: inflammation of pancreas
Not known: diarrhoea

Liver disorders

Rare: increased liver enzymes in the blood
Very rare: jaundice, hepatitis

Skin and subcutaneous tissue disorders

Uncommon: itchiness, rash and hives
Not known: Stevens-Johnson syndrome, drug reaction with eosinophilia and systemic symptoms (DRESS)

Musculoskeletal and connective tissue disorders

Common: muscle pain
Rare: muscle damage
Very rare: joint pain
Not known: immune-mediated necrotising myopathy

Renal and urinary disorders

Very rare: traces of blood in urine

General disorders

Common: weakness
Not known: oedema

The following adverse events have been reported with some statins:

- Sexual dysfunction
- Exceptional cases of interstitial lung disease, especially with long-term therapy.
- tendon disorders, sometimes

complicated by rupture

If you have muscle problems that do not go away even after your doctor has told you to stop taking Rosuvastatin Sandoz, please refer to your doctor. Your doctor may do further tests to diagnose the cause of your muscle problems.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

STORAGE AND DISPOSAL OF ROSUVASTATIN SANDOZ**- Storage**

Keep out of the reach and sight of children.

Do not use your medicine after the expiry date.

Store below 30°C in the original package in order to protect from moisture.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment

PRODUCT DESCRIPTION**- What it looks like****Rosuvastatin Sandoz 10 mg film coated tablet**

Brown, round, film-coated with "RSV 10" debossed on one side.

Rosuvastatin Sandoz 20 mg Film Coated Tablet:

Brown, round, film-coated with "RSV 20" debossed on one side.

- Ingredients**Active ingredient**

Each **Rosuvastatin Sandoz 10 mg** film coated tablet contains 10 mg rosuvastatin as rosuvastatin calcium.

Each **Rosuvastatin Sandoz 20 mg** film coated tablet contains 20 mg

rosuvastatin as rosuvastatin calcium.

Inactive ingredients

Anhydrous Lactose, Silica, Colloidal Anhydrous, Silicified Microcrystalline Cellulose, Maize Starch, Talc, Sodium Stearyl Fumarate, Hypromellose, Mannitol, Macrogol 6000, Titanium Dioxide, Ferric oxide, yellow, Ferric oxide, red.

- MAL numbers

Rosuvastatin Sandoz 10mg Film Coated Tablet: MAL13125015AZ

Rosuvastatin Sandoz 20mg Film Coated Tablet: MAL13125017AZ

MANUFACTURER

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PRODUCT REGISTRATION HOLDER

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