

APO-ROSUVASTATIN TABLETS

Rosuvastatin Calcium (10mg, 20mg)

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What Apo-Rosuvastatin is used for

Apo-Rosuvastatin is indicated as an adjunct treatment in the treatment of hyperlipidemic or dyslipidemic (high level of fat and fatty substance) cases, where diet and exercise is not sufficient in bringing down your cholesterol level.

How Apo-Rosuvastatin works

Apo-Rosuvastatin is a prescription medication containing the active ingredient, rosuvastatin calcium. Apo-Rosuvastatin is a form of HMG-COA reductase inhibitor. It works by blocking an enzyme that is needed by the body to make cholesterol, so this reduces the amount of cholesterol in the blood.

Before you use Apo-Rosuvastatin

- When you must not use it

Do not use this product if you are allergic to Rosuvastatin Calcium or any other ingredients in this medication. (Please refer to **product information**)

You cannot use this medication if you have certain medical condition, such as:

- active liver disease
- kidney impairments
- myopathy (muscle tissue disorder)

Pregnancy and lactation

Do not take Apo-Rosuvastatin if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take Apo-Rosuvastatin if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine

-Before you start to use it

Before taking Apo-Rosuvastatin your doctor needs to know if you have any other medical condition that you may have, including low blood pressure, kidney, liver disease, and/or any that involve your muscle tissues.

Talk to your doctor or pharmacist before taking Apo-Rosuvastatin:

- 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 if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medication might cause complication when taken together with Apo-Rosuvastatin, which includes:

- *Cyclosporins**
- *Protease Inhibitors**
- *Gemfibrosil**
- *Clopidogrel* *
(* increase in blood level of Rosuvastatin.)
- *Coumarin Anticoagulants* (rise in International Normalized Ratio, INR)

How to use Apo-Rosuvastatin

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

The initial dose of Apo-Rosuvastatin, in Asian individuals, should be 5 mg once daily. The maximum dose should not exceed Apo-Rosuvastatin 20 mg once daily.

Your doctor will decide the suitable dose for you with consideration of factors such as your cholesterol level, future cardiovascular risk, and the risk for adverse reaction. It is advised that you follow the instructions given by your doctor.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking Apo-Rosuvastatin for as long as your doctor recommends.

- 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 Emergency Department of your nearest hospital, if you think 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.

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While you are using Apo-Rosuvastatin

- 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 Apo-Rosuvastatin.

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 Apo-Rosuvastatin to anyone else, even if they have the same symptoms or conditions as you.

- Things to be careful of

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side Effects

Like all medicines, Apo-Rosuvastatin can cause side effects, although not everybody gets them.

Rosuvastatin calcium is generally well tolerated. The adverse events seen with rosuvastatin calcium are generally mild and transient.

Side effects that might occur include: abdominal pain

- asthenia (abnormal physical weakness)

- headache
- constipation
- diarrhea
- nausea
- myalgia (muscle weakness)
- dizziness
- insomnia and nightmare
- diabetes (high glucose level in the blood)
- pruritus, rash, urticaria (itching of the skin, spot on the skin)
- myopathy (muscle disease)
- rhabdomyolysis (breakdown of damaged skeletal muscle)
- pancreatitis (inflammation of the pancreas)
- increase hepatic transaminases (a type of enzyme in liver)
- thrombocytopenia (deficiency of platelets in the blood)
- angioedema (swelling of the blood vessels)
- polyneuropathy (degeneration of surrounding nerves)
- memory loss
- depression
- peripheral neuropathy (surrounding nerves disease)
- cough
- dyspnoea (difficulty in breathing)
- Stevens-Johnson syndrome (a type of severe skin reaction)
- Tendon disorders, sometimes complicated by rupture immune-mediated necrotizing myopathy (a type of inflammatory muscle disease)
- jaundice (yellowing of the skin or whites of the eyes)
- hepatitis (inflammation of the liver)
- arthralgia (pain in a joint)
- haematuria (blood in urine)
- gynaecomastia (enlargement of breast in male)
- oedema (swelling)

Unknown frequency:

Myasthenia gravis (a disease causing general muscle weakness including in some cases muscles used when

breathing).

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.

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

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

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 Apo-Rosuvastatin

- Storage

Keep out of the reach and sight of children.

Store below 30°C.

- 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

10 mg: Pink, round, biconvex, film-coated tablet. Engraved "APO" on one side, "ROS" over "10" on the other side.

20 mg: Pink, round, biconvex, film-coated tablet. Engraved "APO" on one side, "ROS" over "20" on the other side.

APO-ROSUVASTATIN TABLETS

Rosuvastatin Calcium (10mg, 20mg)

- Ingredients

- Active ingredient(s)
Rosuvastatin Calcium

- Inactive ingredients

Core tablet:

Lactose Monohydrate,
Microcrystalline Cellulose,
Crospovidone, Magnesium
Stearate, Colloidal Silicon Dioxide.

Coating:

Hydroxypropyl
Methylcellulose,
Hydroxypropyl Cellulose,
Polyethylene Glycol, Titanium
Dioxide, Red Ferric Oxide NF-
Orange Shade.

- MAL number:

Apo-Rosuvastatin 10mg
MAL18106041AZ

Apo-Rosuvastatin 20mg
MAL18106042AZ

Manufacturer

Apotex Inc,
150 Signet Drive, Weston,
Ontario, Canada
M9L IT9

Product Registration Holder

Pharmaforte (M) Sdn Bhd
2, Jalan PJU 3/49, Sunway Damansara,
47810 Petaling Jaya, Selangor, Malaysia.

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18 June 2026

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