

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr**ROSUVASTATIN**

Rosuvastatin Calcium Tablets

Read this carefully before you start taking **ROSUVASTATIN** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **ROSUVASTATIN**.

What is ROSUVASTATIN used for?

ROSUVASTATIN is used along with a change in diet to lower the level of cholesterol and other fats (such as triglycerides) in the blood in:

- adults with high blood cholesterol. In these adults, changes in diet and exercise alone were not effective in lowering their blood cholesterol.
- boys and girls (who have had their period for at least a year) who are 10 to less than 18 years of age with heterozygous familial hypercholesterolemia. This is a genetic condition where high blood cholesterol is inherited from one of the parents. In these children, a change in diet alone was not effective in lowering their blood cholesterol.

ROSUVASTATIN is also used in adults who have no history of heart attack or stroke but who have two or more risk factors as determined by their healthcare professional to reduce the risk of:

- heart attack
- stroke
- undergoing a procedure called coronary artery revascularization. This is a medical procedure used to treat severely blocked arteries due to plaque buildup caused by high blood cholesterol levels.

How does ROSUVASTATIN work?

ROSUVASTATIN belongs to a class of medicines known as "statins", more specifically called HMG- CoA reductase inhibitors. Statins block an enzyme called HMG-CoA reductase in your liver, which is involved in the production of cholesterol in your body. Statins are used along with changes to diet and exercise to help control the amount of cholesterol produced by the body.

ROSUVASTATIN can help your body:

- decrease LDL (bad) cholesterol and triglyceride levels.
- increase HDL (good) cholesterol levels.
- decrease the Total Cholesterol/HDL-Cholesterol Ratio (TC: HDL-C Ratio). The ratio represents the balance between good and bad cholesterol.

If levels of bad cholesterol are too high, they can cause the gradual build-up of cholesterol called plaque on the walls of the blood vessels. Over time, this plaque can build up so much that it narrows the arteries. Narrow arteries can slow or block blood flow to vital organs like the heart and brain. Blocked blood flow can result in a heart attack or stroke. By reducing bad cholesterol levels,

ROSUVASTATIN reduces the risk of heart attack or stroke in adults who have risk factors, and reduces their risk of undergoing a serious medical procedure to treat severely blocked arteries due to plaque buildup.

What are the ingredients in ROSUVASTATIN?

Medicinal ingredient: Rosuvastatin calcium

Non-medicinal ingredients: Colloidal silicon dioxide, corn starch, ferric oxide red, ferric oxide yellow, hypromellose, lactose anhydrous, mannitol, microcrystalline cellulose, polyethylene glycol, sodium stearyl fumarate, talc, titanium dioxide

ROSUVASTATIN comes in the following dosage forms:

Tablets: 5 mg, 10 mg, 20 mg and 40 mg rosuvastatin.

Do not use ROSUVASTATIN if you/your child:

- are allergic to rosuvastatin or any other ingredients in ROSUVASTATIN or its packaging.
- currently have liver disease or unexplained increases in liver enzymes.
- are pregnant or think you might be pregnant.
- are breast-feeding.
- are taking cyclosporine (used to suppress your immune system).
- are taking sofosbuvir/velpatasvir/voxilaprevir (used to treat hepatitis C infection).

Do not use the **40 mg tablet** if you:

- are of Asian descent.
- have risk factors for muscle problems. This includes if you:
 - have had or have a family history of muscular disorders.
 - had any past problems with muscles (pain, tenderness) after using statins such as atorvastatin, fluvastatin, lovastatin, pravastatin, rosuvastatin or simvastatin.
 - currently take fibrates (such as gemfibrozil, fenofibrate and bezafibrate) or niacin (nicotinic acid) (used to lower fat levels in the blood).
 - have thyroid problems.
 - regularly drink **three or more** alcoholic drinks daily.
 - do excessive physical exercise.
 - are above 70 years of age.
 - have liver or kidney problems.
 - have diabetes accompanied with excess fat build-up in your liver.
 - had surgery or other tissue injury.
 - have a condition that causes weakness or frailty.
 - have any conditions or take any medicines that may increase the level of ROSUVASTATIN in the blood. Talk to your healthcare professional if you are unsure.

To help avoid side effects and ensure proper use, talk to your/your child's healthcare professional before you/your child takes ROSUVASTATIN. Talk about any health conditions or problems you/your child may have, including if you:

- have taken ROSUVASTATIN or any other cholesterol-lowering medicines in the past.
- have heart problems.

- have high blood sugar or diabetes, or are at risk for diabetes.
- have been told that you/your child have genetic variations for the SLCO1B1 and/or ABCG2 genes. This may increase the level of ROSUVASTATIN in the blood.
- have a history of liver problems.
- are of Asian descent.
- have risk factors for muscle problems (see section “**Do not use ROSUVASTATIN if**” for details). Your healthcare professional will evaluate your medical condition and decide if you should take ROSUVASTATIN 40 mg.
- have or have had myasthenia (a disease with general muscle weakness including the eye muscles and in some cases muscles used when breathing) as statins may aggravate the condition.

Other warnings you should know about:

ROSUVASTATIN can cause serious side effects, including:

- **Hyperglycemia** (high blood sugar): This may lead to the development of diabetes. Your healthcare professional will monitor your blood sugar level regularly. If you have diabetes, closely monitor your blood sugar while taking ROSUVASTATIN and report any unusual results to your healthcare professional.
- Muscle disorders such as:
 - **Myalgia** (muscle pain)
 - **Rhabdomyolysis** (breakdown of damaged muscle)
 - **Immune-Mediated Necrotizing Myopathy (IMNM)** (a type of autoimmune disease that causes muscle cell death)

Tell your healthcare professional **right away** if you have any muscle pain, tenderness, soreness or weakness while taking ROSUVASTATIN.

See the **Serious side effects and what to do about them** table for more information on these and other serious side effects.

Pregnancy:

- ROSUVASTATIN should **not** be taken during pregnancy. It could harm an unborn baby. Your healthcare professional will discuss the potential risks with you.
- If you are a woman who could become pregnant, your healthcare professional will ask you to use a highly effective birth control method while taking ROSUVASTATIN.
- If you discover that you are pregnant while taking ROSUVASTATIN, **stop** taking the medicine and contact your healthcare professional **as soon as possible**.

Breastfeeding:

- It is not known if ROSUVASTATIN can pass into breast milk and harm a breastfed baby. As such, ROSUVASTATIN should **not** be taken while breastfeeding.
- Talk to your healthcare professional about the best way to feed your baby while you are

taking ROSUVASTATIN.

Check-ups and testing: Your healthcare professional may do blood tests before you start ROSUVASTATIN and during your treatment. These tests will check:

- the level of CoQ10 (an antioxidant) in your blood.
- the amount of sugar (glucose) in your blood.
- that your liver or muscles are working properly.
- the amount of cholesterol and other fats in your blood.

Depending on your test results, your healthcare professional may adjust your dose, temporarily stop or discontinue your treatment with ROSUVASTATIN.

Your healthcare professional may ask you to do a genetic test if you experience side effects while taking ROSUVASTATIN. This test will determine if the side effects you are experiencing are due to your genes. These may affect the way your body processes ROSUVASTATIN.

Tell your healthcare professional about all the medicines you/your child takes, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Serious Drug Interactions

Do not take ROSUVASTATIN with:

- cyclosporine (used to suppress the immune system).
- sofosbuvir/velpatasvir/voxilaprevir (used to treat hepatitis C infection).

Taking ROSUVASTATIN with any of these medicines may cause serious drug interactions. Ask your healthcare professional if you are unsure you are taking them.

The following may also interact with ROSUVASTATIN:

- medicines used to lower blood cholesterol. This includes other statins (e.g., atorvastatin, fluvastatin, lovastatin, pravastatin, simvastatin), fibrates (e.g., gemfibrozil, fenofibrate, bezafibrate), niacin (nicotinic acid), ezetimibe.
- medicines used to treat viral infections such as HIV/AIDS and hepatitis C. This includes antiviral medicines alone or in combination with atazanavir, ritonavir, lopinavir, ombitasvir, paritaprevir, dasabuvir, simeprevir, velpatasvir, grazoprevir, elbasvir, glecaprevir, pibrentasvir, darunavir, tipranavir.
- ketoconazole, fluconazole, itraconazole (used to treat fungal infections).
- spironolactone (used to treat high blood pressure).
- cimetidine (used to treat ulcers of the stomach and intestines).
- dronedarone (used to treat abnormal heart rhythms).
- regorafenib, darolutamide, capmatinib (used to treat cancer).
- febuxostat (used to treat and prevent high blood levels of uric acid).
- fostamatinib, eltrombopag (used to treat low blood platelets).
- teriflunomide (used to treat relapsing remitting multiple sclerosis).
- warfarin, clopidogrel (used to prevent blood clots).

- frequent use of antacids (used to treat heartburn). ROSUVASTATIN should be taken 2 hours apart.
- fusidic acid (used to treat bacterial infections). Your healthcare professional may temporarily stop your treatment with ROSUVASTATIN until your treatment with fusidic acid is complete.
- birth control pills.
- baicalin (a herbal product).
- roxadustat (medicine that increases the number of red blood cells and hemoglobin level in patients with chronic kidney disease)
- enasidenib (used to treat a condition called acute myeloid leukemia)
- tafamidis (used to treat a condition called transthyretin amyloidosis).

How to take ROSUVASTATIN:

Your healthcare professional prescribed this medicine only for you. Do not give your medicine to anyone else because it may harm them, even if their symptoms are the same as yours.

- Take ROSUVASTATIN exactly as your healthcare professional tells you. Keep taking it even if you feel well.
- Take ROSUVASTATIN once a day. Swallow each tablet whole with a drink of water.
- Remember to take ROSUVASTATIN at the same time every day. ROSUVASTATIN can be taken in the morning or evening, with or without food.
- Do not change the dose or stop taking the medicine without first talking to your healthcare professional.
- If you get sick, have an operation, or need medical treatment while taking ROSUVASTATIN, let the healthcare professional or pharmacist know that you are taking ROSUVASTATIN.
- If you have to see a different healthcare professional, for any reason, be sure to tell him/her of any medicines you might be taking, including ROSUVASTATIN.

Remember to get a new prescription from your healthcare professional or a refill from your pharmacy a few days before all your tablets are taken.

ROSUVASTATIN is just part of the treatment the healthcare professional will plan with you to help keep you healthy. Depending on your health and lifestyle, the healthcare professional may recommend:

- a change in diet to:
 - control your weight.
 - reduce your intake of cholesterol and saturated fats.
- exercise that is right for you.
- quitting smoking or avoiding smoky places.
- giving up alcohol or drinking less.

Follow your healthcare professional’s instructions carefully.

Usual dose:

The dose of ROSUVASTATIN prescribed to you will depend on your medical condition and your blood cholesterol level.

To lower blood cholesterol

Adults:

- The recommended starting dose is 10 mg once daily. Some people may be asked to start treatment with 5 mg once a day while others may be asked to start with 20 mg once a day.
- After checking the amount of cholesterol and other fats in your blood, your healthcare professional may decide to adjust your dose until you are taking the amount of ROSUVASTATIN that is right for you. The dosage range for ROSUVASTATIN is 5 to 40 mg once a day.
- The maximum dose is 40 mg per day.

Children and adolescents (10 to less than 18 years of age):

- The recommended starting dose is 5 mg once daily.
- After checking the amount of cholesterol and other fats in your child's blood, the healthcare professional may decide to adjust your child's dose until they are taking the amount of ROSUVASTATIN that is right for them.
- The maximum dose is 10 mg per day.

To lower the risk of heart attack, stroke or undergoing coronary artery vascularization

Adults: The recommended dose is 20 mg once daily.

Overdose:

If you think you, or a person you are caring for, have taken too much ROSUVASTATIN, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you forget to take a dose, take it as soon as you remember. If you do not remember until it is almost time for your next dose, skip the missed dose and take the next dose as scheduled. Do not take a double dose to make-up for a missed dose.

What are possible side effects from using ROSUVASTATIN?

These are not all the possible side effects you may have when taking ROSUVASTATIN. If you experience any side effects not listed here, tell your healthcare professional.

All medicines can cause unwanted side effects. These effects are usually mild and disappear after a short time.

Side effects may include:

- joint pain, swelling of the joints
- muscle spasms or stiffness, shaking (tremors)
- abdominal, chest or back pain
- feeling weak, lack of energy
- nausea, indigestion, constipation, diarrhea, gas

- swelling of the extremities (hands, arms, legs or feet)
- tingling sensation, numbness, weakness or pain in the hands, arms, legs or feet
- sinus infection, runny or stuffy nose
- flu (fever, headache, body aches, cough)
- cough, sore throat
- memory loss, confusion
- trouble sleeping or staying asleep, nightmares
- hives, skin rash or itch
- impotence (inability to get or keep an erection)
- blood in urine
- breast growth in males
- rash that may occur on the skin and sores in the mouth (lichenoid drug eruption)

ROSUVASTATIN can cause abnormal blood test results. Your healthcare professional will decide when to perform blood tests and will interpret the results.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
RARE			
Allergic reactions: difficulty swallowing or breathing, wheezing; drop in blood pressure; feeling sick to your stomach and throwing up; hives or rash; severe itching; swelling of the face, lips, tongue or throat, blistering of the skin and mucous membranes of the lips, eyes, mouth, nasal passages or genitals, high body temperature and enlarged lymph nodes			✓
Liver failure (serious disturbance of liver function): yellow colour to skin, whites of the eyes (jaundice), bleeding easily, swollen abdomen, mental disorientation or confusion, sleepiness, coma.			✓

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<p>Muscle disorders:</p> <ul style="list-style-type: none"> • Myalgia (muscle pain): aching muscles, tenderness or weakness that you cannot explain. • Rhabdomyolysis (breakdown of damaged muscle): muscle tenderness, weakness, red-brown (tea coloured) urine. • Immune-Mediated Necrotizing Myopathy (IMNM) (a type of autoimmune disease that causes muscle cell death): progressive muscle weakness in forearms, thighs, hips, shoulders, neck and back, difficulty standing up, climbing stairs or lifting arms over the head, falling and difficulty getting up from a fall, general feeling of tiredness. <p>These muscle disorders can be accompanied with fever or feeling unwell.</p>		<p>✓</p> <p>✓</p>	<p>✓</p>
<p>Pancreatitis (inflammation of the pancreas): upper abdominal pain, fever, rapid heartbeat, nausea, vomiting, tenderness when touching the abdomen.</p>		<p>✓</p>	
VERY RARE			
<p>Hepatitis (inflammation of the liver): abdominal pain, fatigue, fever, itchiness, light coloured stool, trouble thinking clearly, yellowing of the skin.</p>		<p>✓</p>	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Interstitial lung disease (disease that inflames or scars lung tissue): shortness of breath when at rest that gets worse with exertion, dry cough.			✓
UNKNOWN FREQUENCY			
Depression (sad mood that won't go away): trouble sleeping or sleeping too much, changes in appetite or weight, feelings of worthlessness, guilt, regret, helplessness or hopelessness, withdrawal from social situations, family, gatherings and activities with friends, reduced sex drive and thoughts of death or suicide. If you have a history of depression, your depression may become worse.		✓	
Hyperglycemia (high blood sugar): increased thirst, frequent urination, dry skin, headache, blurred vision and fatigue.	✓		
Myasthenia gravis (muscle weakness): <ul style="list-style-type: none"> • General: difficulty in speaking, chewing and swallowing or weakness of arms and legs and in some cases muscles used when breathing. • Ocular (eye): weak, drooping eyelid(s) causing vision changes. 			✓

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Serious skin reactions: fever, severe rash, swollen lymph glands, blisters and peeling skin that may start in and around the mouth, nose, eyes and genitals and spread to other areas of the body, yellow skin or eyes.			✓
Thrombocytopenia (low blood platelets): bruising or bleeding for longer than usual if you hurt yourself, fatigue and weakness.		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Store ROSUVASTATIN at room temperature (15°C - 30°C).
- Keep out of reach and sight of children.

If you want more information about ROSUVASTATIN:

- Talk to your healthcare professional.
- Find the full Product Monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html> or the manufacturer's website www.sivem.ca or by calling 1 855-788-3153.

This leaflet was prepared by Sivem Pharmaceuticals ULC

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