

PART III: CONSUMER INFORMATION**Pr ROSUVASTATIN**

Rosuvastatin Calcium Tablets
5 mg, 10 mg, 20 mg and 40 mg
Manufacturer's Standard

This leaflet is part III of a three-part "Product Monograph" published when ROSUVASTATIN was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about ROSUVASTATIN. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION**What ROSUVASTATIN is used for:**

Your doctor has prescribed these pills to help lower your cholesterol or other fats in the blood (such as triglycerides) and lower the risk of heart attacks and strokes.

ROSUVASTATIN may be prescribed in children 10 to 17 years of age with heterozygous familial hypercholesterolemia (an inherited condition causing high cholesterol levels in the blood) to lower cholesterol levels. Children require supervision from adult care givers during treatment with ROSUVASTATIN (adult care givers should read the information provided below before their child begins treatment with ROSUVASTATIN).

What ROSUVASTATIN does:

Rosuvastatin belongs to the class of medications known as "statins", more specifically called HMG-CoA reductase inhibitors. HMG-CoA reductase is an enzyme involved in regulating cholesterol levels 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.

What is cholesterol?

Cholesterol is one of several fatty substances in the blood that the body needs to function. And it is important to our health. Our bodies use cholesterol in a number of ways; for example, to produce bile acids that help you digest fat.

High cholesterol levels may not make you feel or look sick. However, too much cholesterol in your blood can be unhealthy; it builds up on the artery walls and can lead to

the signs and symptoms of cardiovascular disease (heart disease).

There are two very different types of cholesterol.

LDL cholesterol

If levels of LDL 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.

HDL cholesterol

HDL carries the LDL cholesterol away from the blood vessel walls to the liver, where it can be removed from the body. A higher level of HDL cholesterol is good.

Important cholesterol targets

There are a few important measures that relate to your cholesterol. In addition to your HDL and LDL cholesterol, your doctor may also track your TC:HDL-C Ratio.

Lowering LDL cholesterol and Ratio

There are many things you can do, depending on your health and lifestyle, to help lower LDL cholesterol, increase HDL cholesterol and lower your TC: HDL-C Ratio. Your doctor may recommend:

- A change in your diet to control your weight and/or lower your cholesterol.
- Exercise that is right for you.
- Quitting smoking and avoiding smoky places.
- Giving up alcohol or drinking less.

Follow your doctor's instructions carefully.

When ROSUVASTATIN should not be used:

Do not take ROSUVASTATIN if you:

- Currently have liver disease.
- Are pregnant or think you might be pregnant. If you become pregnant while taking ROSUVASTATIN, discontinue use immediately and discuss with your doctor, as ROSUVASTATIN should not be used by pregnant women.
- Are breast-feeding.
- Have ever had an allergic reaction to the active ingredient or any of the other ingredients in ROSUVASTATIN. (**see What the nonmedicinal ingredients are:**)
- Are taking a drug called cyclosporine (used, for example, after organ transplant).
- Are taking sofosbuvir/velpatasvir/voxilaprevir, used to treat chronic hepatitis C virus infection.

What the medicinal ingredient is:

Rosuvastatin calcium.

What the nonmedicinal ingredients are:

crospovidone, hydroxypropyl cellulose, hydroxypropyl methyl cellulose, iron oxide yellow (5 mg tablets), iron oxide red (10 mg, 20 mg and 40 mg tablets), lactose monohydrate, microcrystalline cellulose, magnesium stearate, sodium bicarbonate, titanium dioxide and triacetin.

ROSUVASTATIN contains lactose and colouring agents but does not contain gluten.

What dosage form it comes in:

Film-coated tablets: 5 mg, 10 mg, 20 mg, and 40 mg.

WARNINGS AND PRECAUTIONS

Pregnancy

ROSUVASTATIN should not be used by pregnant women. Cholesterol compounds are essential elements for the development of a fetus. Cholesterol-lowering drugs can harm the fetus. If you become pregnant, discontinue use immediately and tell your doctor.

If you are of childbearing age, discuss with your doctor the potential risks and the importance of birth control methods.

Before taking your ROSUVASTATIN tablets, tell your doctor or pharmacist if you:

- Have thyroid problems.
- Regularly drink *three or more* alcoholic drinks daily.
- Have a family history of muscular disorders.
- Had any past problems with your muscles (pain, tenderness), after using an HMG-CoA reductase inhibitor (statin) such as atorvastatin (LIPITOR®), fluvastatin (LESCOL®), lovastatin (MEVACOR®), pravastatin (PRAVACHOL®), rosuvastatin (CRESTOR®) or simvastatin (ZOCOR®), or have developed an allergy or intolerance to them.
- Have kidney or liver problems.
- Have diabetes.
- Have undergone surgery or other tissue injury.
- Do excessive physical exercise.

Slightly increased blood sugar can occur when you take ROSUVASTATIN. You are likely to be at risk of developing diabetes if you have high levels of sugar and fats in your blood, are overweight and have high blood pressure. Discuss with the doctor your risk of developing diabetes.

INTERACTIONS WITH THIS MEDICATION

Sometimes drugs can interact with other drugs, so tell your doctor or pharmacist if you are taking any other medications, including prescription, non-prescription and

natural health products. In particular, tell your doctor if you are taking any of the following:

- Any other cholesterol-lowering medications such as fibrates (gemfibrozil, fenofibrate), niacin or ezetimibe.
- Warfarin, clopidogrel (or any other drug for thinning the blood).
- Antiviral medications alone or in combination such as atazanavir, dasabuvir, elbasvir, glecaprevir, grazoprevir, lopinavir, ritonavir, ombitasvir, paritaprevir, pibrentasvir, simeprevir, sofosbuvir, velpatasvir, and voxilaprevir (used to fight infections, including the HIV infection or Hepatitis C infection).
- Regorafenib and darolutamide (used to treat cancer).
- Antacids (frequent use) and ROSUVASTATIN should be taken 2 hours apart.
- Cyclosporine (used after organ transplant).
- Fusidic acid (an antibiotic agent). Your doctor may temporarily stop your treatment of ROSUVASTATIN until the treatment with fusidic acid is complete.

PROPER USE OF THIS MEDICATION

Your doctor 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.

Always follow your doctor's instructions carefully and keep taking your medicine even if you feel well.

- Swallow each tablet whole with a drink of water. Take ROSUVASTATIN as a single dose.
- Remember to take ROSUVASTATIN at the same time every day. It does not matter if you take ROSUVASTATIN with or without food, or in the morning or evening.
- Do not change the dose or stop taking the medicine without first talking to your doctor.
- If you get sick, have an operation, or need medical treatment while you are taking ROSUVASTATIN, let the doctor or pharmacist know that you are taking ROSUVASTATIN.
- If you have to see a different doctor, 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 doctor or a refill from your pharmacy a few days before all your tablets are taken.

Usual dose:

Adults

Treatment with ROSUVASTATIN is usually started with one 10 mg tablet taken once daily. Some people may be asked to start treatment with one 5 mg tablet taken once a day while others may be asked to start with one 20 mg tablet taken once a day.

After checking the amount of lipids in your blood, your doctor may decide to adjust your dose until you are taking the amount of ROSUVASTATIN that is right for you. The maximum daily dose is 40 mg.

Children 10 to 17 years of age with heterozygous familial hypercholesterolemia

Treatment with ROSUVASTATIN is usually started at a dose of 5 mg once daily. After checking the amount of lipids in your blood, your doctor may decide to adjust your dose until you are taking the amount of ROSUVASTATIN that is right for you. The maximum daily dose is 10 mg.

Overdose:

There is no specific treatment in the event of an overdose.

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

Missed dose:

Do not take a double dose. If you miss taking a tablet, take it as soon as you can. But if it is almost time for your next dose, skip the missed dose and just take the next dose.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Most people do not have side effects when taking ROSUVASTATIN. However, all medicines can cause unwanted side effects. These effects are usually mild and disappear after a short time.

Check with your doctor or pharmacist promptly if any of the following persist or become troublesome:

- Stomach pain
- Headache
- Constipation
- Dizziness
- Feeling sick

Less commonly, some people may have other side effects such as a skin rash, itching and hives.

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

Possible side effects reported with some statins: breathing problems including persistent cough and/or shortness of breath or fever; confusion, poor memory, mood problems including depression; problems sleeping including insomnia and nightmares; erectile dysfunction; numbness, tingling, weakness or pain, usually in your hands or feet, but this may

also occur in other areas of your body (peripheral neuropathy).

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom/Effect		Talk with your doctor or pharmacist		Stop taking drug and seek immediate emergency medical attention
		Only if severe	In all cases	
Rare	Muscle pain that you cannot explain		✓	
	Muscle tenderness or weakness, or joint pain		✓	
	Breast enlargement in women and men (gynecomastia)		✓	
	Generalized weakness, especially if you do not feel well		✓	
	Jaundice or hepatitis symptoms like brownish or discoloured urine		✓	
	Difficulty in breathing or swallowing			✓
	Allergic reaction (symptoms include swelling in the mouth, tongue, face and throat, severe itching, rash, raised lumps (hives), blistering of the skin and mucous membranes of			✓

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom/Effect	Talk with your doctor or pharmacist		Stop taking drug and seek immediate emergency medical attention
	Only if severe	In all cases	
the lips, eyes, mouth nasal passages or genitals)			
Liver damage: yellowing of the skin or eyes, flu-like symptoms			✓
Very Rare Inflamed pancreas (pancreatitis) symptoms, such as severe stomach pain		✓	
Memory loss		✓	
Unknown Increased blood sugar: frequent urination, thirst and hunger	✓		
Decrease of platelets in the blood (characterized by easy or excessive bleeding such as bruising easily, nosebleed and bleeding gums)		✓	

This is not a complete list of side effects. For any unexpected effects while taking ROSUVASTATIN, contact your doctor or pharmacist.

HOW TO STORE IT

- KEEP YOUR TABLETS IN A SAFE PLACE where children cannot see or reach them. Your tablets could harm them.
- Keep your medicine at room temperature (15°C-30°C), away from warm or damp places like bathrooms or kitchens.
- Keep your tablets in the package they came in. Keep container tightly closed.
- If your doctor decides to stop your treatment, return your tablets to your pharmacist for disposal.
- Do not take your tablets after the expiry date on the package.

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.

MORE INFORMATION

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 Consumer Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website (www.sivem.ca) or by contacting Sivem Pharmaceuticals ULC at: Phone: 1-855-788-3153.

This leaflet was prepared by:
Sivem Pharmaceuticals ULC
4705 Dobrin Street
Saint-Laurent, Quebec, Canada
H4R 2P7

www.sivem.ca
Last revised: June 4, 2021