

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **NB-ATORVASTATIN**

Atorvastatin Calcium Tablets

Read this carefully before you start taking **NB-Atorvastatin** 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 **NB-Atorvastatin**.

Serious Warnings and Precautions

- NB-Atorvastatin may cause 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)They may not go away even after you stop taking NB-Atorvastatin.
- Tell your healthcare professional **right away** if you have any muscle pain, tenderness, soreness or weakness while taking NB-Atorvastatin.

What is NB-Atorvastatin used for?

NB-Atorvastatin is used along with changes in lifestyle, including diet, to lower the level of cholesterol and other fats (such as triglycerides) in the blood in:

- adults with high blood cholesterol
- boys and girls (who already started their period) 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. These children have high blood cholesterol when dieting and have:
 - a family history of premature cardiovascular disease (heart and blood vessel problems); or
 - two or more other cardiovascular risk factors as determined by their healthcare professional.

NB-Atorvastatin is also used to lower the risk of heart attack in adults with:

- coronary heart disease. This is a heart condition that happens when the arteries of the heart become narrower and cannot deliver enough blood to the heart. This is due to a buildup of plaque (fatty deposits) inside the artery walls.
- high blood pressure who have no evidence of coronary heart disease, but have three or more risk factors as determined by their healthcare professional

NB-Atorvastatin is used to lower the risk of heart attack and stroke in adults with:

- type 2 diabetes and high blood pressure who have no evidence of coronary heart disease, but have other risk factors as determined by their healthcare professional.

NB-Atorvastatin is just part of the treatment the healthcare professional will plan with you to help keep you or your child healthy. Depending on your/your child's health and lifestyle, the healthcare professional may recommend:

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

Follow the instructions of your/your child's healthcare professional carefully.

How does NB-Atorvastatin work?

NB-Atorvastatin 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. NB-Atorvastatin is used along with changes to your lifestyle to help control the amount of cholesterol in your blood.

NB-Atorvastatin can help your body:

- Decrease LDL (bad) cholesterol, triglyceride levels and other fats in the blood
- Increase HDL (good) cholesterol
- Decrease the Total Cholesterol HDL-Cholesterol Ratio (TC-HDL-C Ratio). This ratio represents the balance between good and bad cholesterol.

This in turn also reduces the risk of heart attack and stroke in adults who:

- have multiple risk factors for developing cardiovascular problems
- have coronary heart disease

What are the ingredients in NB-Atorvastatin?

Medicinal ingredient: atorvastatin calcium.

Non-medicinal ingredients: cellulose microcrystalline, calcium carbonate, lactose monohydrate, croscarmellose sodium, hydroxypropylcellulose, polysorbate 80, magnesium stearate, hypromellose 2910, polyethylene glycol 6000 and titanium dioxide.

NB-Atorvastatin comes in the following dosage forms:

Tablets: 10 mg, 20 mg, 40 mg and 80 mg atorvastatin (as atorvastatin calcium trihydrate).

Do not use NB-Atorvastatin if you/your child:

- are allergic to atorvastatin calcium or any other ingredients in NB-Atorvastatin or its packaging
- have active liver disease or unexplained increases in liver enzymes
- are pregnant or think you/they might be pregnant
- are breast-feeding
- are taking medicines used to treat hepatitis C, such as telaprevir, boceprevir, glecaprevir/pibrentasvir, elbasvir/grazoprevir, simeprevir, velpatasvir/sofosbuvir, ledipasvir/sofosbuvir.
- are taking cyclosporine, a medicine used to suppress your immune system

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

- have previously taken any cholesterol-lowering medicines in the past. This includes:
 - statins, such as atorvastatin, fluvastatin, lovastatin, pravastatin, rosuvastatin or simvastatin
 - fibrates such as gemfibrozil, fenofibrate and bezafibrate
 - niacin (nicotinic acid)
- have had a stroke or a mini stroke
- are currently taking any other medicines
- have kidney or liver problems
- are above 65 years of age
- regularly drink **three or more** alcoholic drinks daily
- have a family history of muscular disorders
- had any past problems with the muscles (pain, tenderness) after using medicines such as atorvastatin, fluvastatin, lovastatin, pravastatin, rosuvastatin or simvastatin.
- have thyroid problems
- do excessive physical exercise
- have diabetes
- have undergone surgery or other tissue injury
- feel weak or frail

Other warnings you should know about:

NB-Atorvastatin can cause serious side effect, including:

- **Hyperglycemia** (high blood sugar):
 - This may lead to the development of type 2 diabetes.
 - Your healthcare professional will monitor your blood sugar level regularly and may adjust your dose during treatment.
 - If you have diabetes, closely monitor your blood sugar while taking NB-Atorvastatin and report any unusual results to your healthcare professional.

- **Liver failure** (serious disturbances of liver function)
- **Allergic reactions**

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

Pregnancy:

- NB-Atorvastatin 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 NB-Atorvastatin.
- If you discover that you are pregnant while taking NB-Atorvastatin, **stop** taking the medicine and contact your healthcare professional **as soon as possible**.

Breastfeeding:

- It is not known whether NB-Atorvastatin can pass into breast milk and harm a breastfed baby. As such, NB-Atorvastatin is **not** recommended during breastfeeding.
- Talk to your healthcare professional about ways to feed your baby while taking NB-Atorvastatin.

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

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

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

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

Serious Drug Interactions

Do not take NB-Atorvastatin with:

- Medicines used to treat hepatitis C. These include telaprevir, boceprevir, glecaprevir/pibrentasvir, elbasvir/grazoprevir, simeprevir, ledipasvir/sofosbuvir and velpatasvir/sofosbuvir.
- Cyclosporine, a medicine used to suppress the immune system.

Inform your healthcare professional before taking NB-Atorvastatin with:

- Medicines used to treat HIV/AIDS. These include efavirenz, nelfinavir, lopinavir/ritonavir, tipranavir, ritonavir, saquinavir, darunavir and fosamprenavir.

Taking NB-Atorvastatin with any of these medicines may cause serious drug interactions. Ask your healthcare professional if you are unsure.

The following may interact with NB-Atorvastatin:

- Medicines used to lower blood cholesterol. These include niacin (nicotinic acid), fibrates, such as gemfibrozil, fenofibrate, and bezafibrate, and bile acid resins, such as cholestyramine and colestipol.
- Medicines used to treat bacterial infections. These include erythromycin, clarithromycin, azithromycin, fusidic acid and rifampin.
- Letemovir – used to treat a viral infection caused by the cytomegalovirus (CMV)
- Itraconazole, ketoconazole – used to treat fungal infections
- Nefazodone – used to treat depression
- Digoxin – used to treat heart conditions
- Amlodipine, quinapril, diltiazem – used to treat high blood pressure and other heart conditions
- Antacids – used to treat heartburn (indigestion)
- Cimetidine – used to treat ulcers of the stomach and intestines
- Colchicine – used to treat gout
- Birth control medication
- Hormone replacement therapy
- Grapefruit juice

How to take NB-Atorvastatin:

Take NB-Atorvastatin:

- exactly as your healthcare professional tells you
- once a day
- preferably in the evening
- with or without food. However, do not drink grapefruit juice while taking NB-Atorvastatin. Grapefruit juice increases the level of NB-Atorvastatin in your blood and makes side effects more likely.

Follow the plan your healthcare professional is recommending for diet, exercise and weight control while taking NB-Atorvastatin.

Usual dose:

The dose of NB-Atorvastatin prescribed to you will depend on your condition and/or your blood cholesterol level. Your healthcare professional may change your dose depending on your response to NB-Atorvastatin.

To lower blood cholesterol

Adults:

- The recommended starting dose is 10 mg or 20 mg once daily, depending on your required cholesterol reduction.
- Patients who need a large reduction in blood cholesterol (more than 45%) may start at 40 mg once daily.
- The dosage range for NB-Atorvastatin is 10 to 80 mg once daily.
- The maximum dose is 80 mg per day.

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

- The recommended starting dose is 10 mg once daily.
- The maximum recommended dose is 20 mg per day.

To prevent heart attack and stroke

Adults: The recommended dose is 10 to 80 mg once daily.

Overdose:

If you think you, or a person you are caring for, have taken too much NB-Atorvastatin, 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 double the dose.

What are possible side effects from using NB-Atorvastatin?

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

Side effects may include:

- Diarrhea
- Abdominal pain or discomfort
- Nausea
- Vomiting
- Gas
- Sore throat or stuffy nose
- Nosebleeds
- Dizziness
- Memory loss or confusion
- Loss of sensation in part of your body
- Tingling sensation or pain in the hands, arms, legs or feet
- Nightmares

- Difficulty falling asleep
- Hair loss
- Skin rash or itch
- Joint pain
- Impotence (inability to get or keep an erection)
- Breast growth in males

NB-Atorvastatin 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	
UNCOMMON			
Cholestasis (decrease in bile flow from the liver): jaundice (yellowing of the skin or whites of eyes), dark urine, light coloured stools		✓	
RARE			
Allergic Reactions: difficulty swallowing or breathing, wheezing; drop in blood pressure; feeling sick to your stomach and throwing up; hives or rash; swelling of the face, lips, tongue or throat.			✓
Chest Pain			✓
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			✓
Muscle Disorders: – Myalgia (muscle pain): aching muscles, tenderness or weakness that you cannot explain		✓	

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	
<ul style="list-style-type: none"> – 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>		✓	✓
Pancreatitis (inflammation of the pancreas): upper abdominal pain, fever, rapid heartbeat, nausea, vomiting, tenderness when touching the abdomen			✓
Tendon rupture : popping or snapping sound when injury occurs, feeling of being kicked in the calf, very painful calf, difficulty walking, inability to stand on the toes on the injured leg, swollen or bruised calf			✓
Thrombocytopenia (low blood platelets): bruising or bleeding for longer than usual if you hurt yourself, fatigue and weakness			✓
VERY RARE			
Ewing's Sarcoma in children (a type of tumour that forms in bone or soft		✓	

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	
tissue): Presence of a lump, pain, swelling or tenderness near the tumour, bone pain, unexplained broken bone, feeling tired, fever with no cause, weight loss			
Hepatitis (inflammation of the liver): abdominal pain, fatigue, fever, itchiness, light coloured stool, trouble thinking clearly, yellowing of the skin		✓	
Interstitial lung disease (disease that inflame or scar lung tissue): shortness of breath when rest that gets worse with exertion, dry cough			✓
UNKNOWN			
Depression (sad mood that won't go away): difficulty 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 libido (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	✓		

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 NB-Atorvastatin between 15°C and 30°C, away from warm or damp places like the bathroom or kitchen. Protect from moisture.
- Keep out of reach and sight of children.

If you want more information about NB-Atorvastatin:

- 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>; the manufacturer's website www.nbpharmainc.com or by calling 1-855-662-1814.

This leaflet was prepared by NB Pharma Inc.

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