

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr MYLAN-AMLODIPINE/ATORVASTATIN

Amlodipine besylate and atorvastatin calcium tablets

Read this carefully before you start taking **MYLAN-AMLODIPINE/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 **MYLAN-AMLODIPINE/ATORVASTATIN**.

What is MYLAN-AMLODIPINE/ATORVASTATIN used for?

MYLAN-AMLODIPINE/ATORVASTATIN contains two active ingredients, amlodipine and atorvastatin. MYLAN-AMLODIPINE/ATORVASTATIN is used in adults who need both active ingredients.

MYLAN-AMLODIPINE/ATORVASTATIN is used to:

- Treat high blood pressure (hypertension).
- Prevent chest pain attacks (angina).
- Lower cholesterol or other fats in the blood such as triglycerides.

How does MYLAN-AMLODIPINE/ATORVASTATIN work?

MYLAN-AMLODIPINE/ATORVASTATIN contains two active ingredients, amlodipine and atorvastatin. Amlodipine belongs to a group of medications called calcium channel blockers. They block the transfer of calcium into the heart and blood vessels. This relaxes the blood vessels which improves blood flow, making it easier for the heart to pump blood.

Atorvastatin belongs to a group of medicines called HMG-CoA reductase inhibitors, or “statins”. Atorvastatin decreases “bad” cholesterol (low-density lipoprotein) and triglyceride levels, while increasing “good” cholesterol (high-density lipoprotein). High levels of cholesterol and other fats can cause heart disease by clogging the blood vessels that feed blood and oxygen to the heart.

What are the ingredients in MYLAN-AMLODIPINE/ATORVASTATIN?

Medicinal ingredients: amlodipine besylate and atorvastatin calcium.

Non-medicinal ingredients: calcium carbonate, colloidal silicon dioxide (anhydrous), croscarmellose sodium, hydroxypropyl cellulose, magnesium stearate, microcrystalline cellulose, opadry II white or opadry II blue, polysorbate 80, pregelatinized starch, and purified water.

MYLAN-AMLODIPINE/ATORVASTATIN comes in the following dosage forms:

Tablets:

- 5mg/10mg (white)
- 5mg/20mg (white)
- 5mg/40mg (white)
- 5mg/80mg (white)
- 10mg/10mg (blue)
- 10mg/20mg (blue)
- 10mg/40mg (blue)
- 10mg/80mg (blue)

Do not use MYLAN-AMLODIPINE/ATORVASTATIN if:

- you are allergic to amlodipine besylate, atorvastatin calcium or any of the other ingredients in MYLAN-AMLODIPINE/ATORVASTATIN.
- you have been diagnosed with low blood pressure.
- you have active liver disease or unexplained increases in liver enzymes.
- you are pregnant or breast-feeding. If you become pregnant, tell your doctor right away.
- you are taking medication containing glecaprevir/pibrentasvir (MAVIRET™), elbasvir/grazoprevir, velpatasvir/sofosbuvir, or ledipasvir/sofosbuvir.
- you are taking medication containing cyclosporine (SANDIMMUNE®, NEORAL®).

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

- have had a stroke or a mini stroke called a transient ischemic attack (TIA)
- regularly drink *three or more* alcoholic drinks daily
- have kidney or liver problems
- are 65 years of age or older
- are taking fusidic acid
- are taking medicines containing digoxin, ketoconazole, clarithromycin or ritonavir
- have a narrowed heart valve (aortic stenosis)
- are at a risk for developing myopathy (muscle aching or weakness). Risk factors include if you:
 - have ever had muscle problems or have a family history of muscle problems
 - have ever had muscle problems during treatment with statins, such as atorvastatin (LIPITOR®), fluvastatin, lovastatin, pravastatin, rosuvastatin (CRESTOR®) or simvastatin (ZOCOR®)
 - are taking other medicines to lower cholesterol such as fibrates (gemfibrozil, fenofibrate) or niacin
 - have thyroid problems
 - drink large amounts of alcohol
 - do excessive physical exercise
 - are 65 years of age or older
 - have kidney or liver problems
 - have diabetes with hepatic fatty change
 - recently had surgery or suffered a trauma

Other warnings you should know about:

MYLAN-AMLODIPINE/ATORVASTATIN can cause serious side effects, including:

- Worsened angina (chest pain) and heart attacks.
- Hypotension (low blood pressure). Your blood pressure should be carefully monitored.
- Hypersensitivity (allergic reaction). This has been seen with other statins. If you have allergic reactions, your healthcare professional may stop your treatment.
- Hyperglycaemia (high blood sugar). Slightly increased blood sugar can occur when you take MYLAN-AMLODIPINE/ATORVASTATIN. Discuss with your healthcare professional your risk of developing diabetes.
- Jaundice. If during treatment you develop jaundice, tell your doctor right away. Your treatment with MYLAN-AMLODIPINE/ATORVASTATIN may need to be stopped.
- Myalgia (muscle pain) and Rhabdomyolysis (muscle tenderness or weakness). Tell your doctor right away if you have muscle pain, tenderness or weakness especially if you are also feeling unwell or have a fever. Your healthcare professional will perform tests and your treatment with MYLAN-AMLODIPINE/ATORVASTATIN may need to be stopped.

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

Liver Disease: If during treatment you develop liver problems, tell your doctor right away. Your treatment with MYLAN-AMLODIPINE/ATORVASTATIN may need to be stopped.

Laboratory Testing: MYLAN-AMLODIPINE/ATORVASTATIN can cause abnormal blood test results. Your doctor will decide when to perform blood tests and will interpret the results.

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

The following may interact with MYLAN-AMLODIPINE/ATORVASTATIN:

- Medicines that reduce inflammation such as corticosteroids and colchicine
- Medicines used to suppress the immune system such as tacrolimus, sirolimus, and everolimus
- Medicines used to treat cancer such as temsirolimus
- Medicine used to regulate cholesterol levels such as gemfibrozil, fenofibrate, bezafibrate, and niacin (nicotinic acid)
- Medicine used to treat heartburn called cimetidine
- Medicines used to treat bacterial, fungal, or viral infections such as letermovir, fusidic acid, rifampin, erythromycin, clarithromycin, ketoconazole and itraconazole
- Medicine used to treat depression called nefazodone
- Medicine used to treat heart failure called digoxin
- Medicines used to treat blood pressure such as spironolactone, diltiazem and beta-blockers
- Medicines used to treat HIV such as efavirenz, tipranavir/ritonavir, ritonavir, lopinavir/ritonavir, fosamprenavir, nelfinavir mesylate, and darunavir
- Medicine used to treat erectile dysfunction called sildenafil (VIAGRA®)
- Medicines used to treat stomach acidity called antacids
- Medicine used to relax muscles called dantrolene
- Oral contraceptives
- Herbal medicines such as St. John's Wort

- Grapefruit or grapefruit juice

How to take MYLAN-AMLODIPINE/ATORVASTATIN:

- Take MYLAN-AMLODIPINE/ATORVASTATIN exactly as your healthcare professional has told you. Do not increase, decrease or stop taking MYLAN-AMLODIPINE/ATORVASTATIN without first talking to your healthcare professional. Check with your healthcare professional if you are not sure.
- Take one tablet daily with or without food. Swallow tablet with water.
- Continue to take your medicine even if you do not feel better. It may take a number of weeks for your medicine to start working.

MYLAN-AMLODIPINE/ATORVASTATIN is just part of the treatment your healthcare professional will plan with you to help keep you healthy. Depending on the condition of your health and your lifestyle, your doctor may recommend:

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

Follow the plan that you and your doctor make.

Usual dose:

Your healthcare professional will determine which dose is right for you. Based on your response and tolerability your healthcare professional may increase your dose. If you are elderly or have liver or kidney problems your healthcare professional may prescribe a lower dose.

Overdose:

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

Missed Dose:

If you missed a dose of this medication, take it as soon as you remember. But if it is almost time for your next dose, skip the missed dose and continue with your next scheduled dose. Do not double dose.

What are possible side effects from using MYLAN-AMLODIPINE/ATORVASTATIN?

These are not all the possible side effects you may feel when taking MYLAN-AMLODIPINE/ATORVASTATIN. If you experience any side effects not listed here, contact your healthcare professional.

Side effects include:

- stomach pain or upset, vomiting or throwing up, loss of appetite and inability to eat, or malaise (general feeling of being unwell), burping

- gas, constipation, diarrhea
- headache, neck pain
- fever
- hair loss
- skin rash, hives, itchiness
- insomnia (difficulty sleeping), drowsiness, fatigue, nightmares
- erectile dysfunction (inability to develop or maintain an erection of the penis)
- blurred vision, ringing in the ears
- breathing problems including persistent cough and/or shortness of breath or fever
- mood related disorders including depression
- poor memory, confusion and memory loss

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	
COMMON			
Peripheral edema (swelling of the legs or hands caused by fluid retention): swollen or puffy legs or hands, feeling heavy, achy or stiff	✓		
RARE			
Abnormal vision		✓	
Allergic Reaction: 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			✓
Arrhythmia (abnormal heart rhythms): rapid, slow or irregular heartbeat		✓	
Asthenia (lack or loss of strength)		✓	
Hypotension (low blood pressure): dizziness, fainting, light-headedness, blurred vision, nausea, vomiting, fatigue (may occur when you go from lying or sitting to standing up)	✓		
Increased frequency, severity, duration of angina (chest pains)		✓	
Jaundice (build up of bilirubin in the blood): yellowing of the skin and eyes, dark urine, light coloured stool, itching all over your body		✓	
Myalgia (muscle pain): aching		✓	

muscles, tenderness or weakness			
Myocardial infarction (heart attack): pressure or squeezing pain between the shoulder blades, in the chest, jaw, left arm or upper abdomen, shortness of breath, dizziness, fatigue, light-headedness, clammy skin, sweating, indigestion, anxiety, feeling faint and possible irregular heartbeat			✓
Pancreatitis (inflammation of the pancreas): upper abdominal pain, fever, rapid heart beat, nausea, vomiting, tenderness when touching the abdomen		✓	
Paraesthesia (pins and needles): sensation of tingling, pain or numbness in hands, fingers and toes	✓		
Rhabdomyolysis (breakdown of damaged muscle): muscle tenderness, weakness, red-brown (tea-coloured) urine		✓	
Shortness of breath		✓	
UNKNOWN			
Extrapyramidal symptoms: muscle stiffness, body spasms, upward eye rolling, exaggeration of reflexes, drooling, difficulty moving how and when you want			✓
Hyperglycaemia (high blood sugar): increased thirst, frequent urination, dry skin, headache, blurred vision and fatigue	✓		
Liver Disease (worsening of liver function): confusion, coma, death			✓

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

Keep your medicine at 15-30°C (room temperature)

Keep out of reach and sight of children.

If you want more information about MYLAN-AMLODIPINE/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 <http://www.viatris.ca>, or by calling 1-844-596-9526.

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