

PART III: CONSUMER INFORMATION

PrGD[®]-AMLODIPINE
(Amlodipine Besylate Tablets)

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

ABOUT THIS MEDICATION

What the medication is used for:

GD-amlodipine has been prescribed to you for:

- The treatment of high blood pressure (hypertension), or
- The management of a type of chest pain called angina.

GD-amlodipine can be used by itself or with other medicines to treat these conditions.

What it does:

GD-amlodipine is a type of medicine known as a calcium channel blocker (CCB).

GD-amlodipine relaxes your blood vessels, which lets your blood flow more easily and helps lower your blood pressure.

GD-amlodipine controls chest pain by improving the supply of blood and oxygen to the heart and by reducing its workload.

When it should not be used:

Do not use GD-amlodipine if you:

- Are allergic to amlodipine (the active ingredient in GD-amlodipine), or to the inactive ingredients listed under "What the nonmedicinal ingredients are" below.
- Have ever had an allergic reaction to a similar type of drug.
- Have very low blood pressure (less than 90 mmHg systolic).
- Are breast-feeding. Do not breast-feed while taking GD-amlodipine.

What the medicinal ingredient is:

Amlodipine besylate

What the nonmedicinal ingredients are:

Dibasic calcium phosphate anhydrous, magnesium stearate, microcrystalline cellulose and sodium starch glycolate.

What dosage forms it comes in:

Tablets 2.5 mg, 5 mg and 10 mg amlodipine

WARNINGS AND PRECAUTIONS

BEFORE you use GD-amlodipine talk to your doctor, nurse or pharmacist if you:

- Ever had heart or blood vessel diseases.
- Have aortic stenosis (narrowing of a valve of your heart).
- Have liver or kidney problems.
- Are pregnant, or plan to become pregnant.

GD-amlodipine should not be used during pregnancy unless your doctor tells you otherwise.

- Are older than 65 years.

GD-amlodipine may occasionally cause low blood pressure (hypotension). Your blood pressure should be carefully monitored, especially if you have had a stroke or take other drugs to lower your blood pressure.

If you take GD-amlodipine together with a drug known as beta-blockers (e.g. acebutolol, atenolol, metoprolol, nadolol), do not suddenly stop using the beta-blocker. If your doctor advises you to discontinue use of the beta-blocker, your dose should be decreased slowly, as recommended by your doctor, before stopping it completely.

GD-amlodipine is not recommended for use in children less than 6 years of age.

INTERACTIONS WITH THIS MEDICATION

As with most medicines, interactions with other drugs are possible. Tell your doctor, nurse or pharmacist about all the medicines you take, including drugs prescribed by other doctors, vitamins, minerals, natural supplements, or alternative medicines. Also mention if you drink alcoholic beverages.

Drug-Drug interaction:

Drugs that may interact with GD-amlodipine include:

- Cyclosporin
- Clarithromycin, Erythromycin (antibiotics)
- Diltiazem
- Azole antifungals (e.g. ketoconazole, itraconazole)
- HIV protease inhibitors (e.g. ritonavir)
- Beta-blockers
- Sildenafil (VIAGRA)
- Statin drugs used to treat high cholesterol (e.g. Simvastatin, Atorvastatin)
- Tacrolimus (an anti-rejection drug)
- Sirolimus, temsirolimus, everolimus

Drug-Herb interaction:

- St-John Wort

Drug-Food interaction:

Do not eat grapefruit or drink grapefruit juice while on GD-amlodipine.

PROPER USE OF THIS MEDICATION

Take GD-amlodipine exactly as prescribed by your doctor, nurse or pharmacist. It may be easier to take your dose if you do it at the same time every day, such as with breakfast or dinner, or at bedtime. Do not stop taking your medication without having first informed your doctor.

Usual dose:

For both high blood pressure and chest pain, the recommended initial dose of GD-amlodipine is 5 mg once daily. If necessary,

your doctor may increase your dose to a maximum dose of 10 mg once daily.

Use in Patients with liver disease:

The starting dose is 2.5 mg once daily and can be gradually increased by your doctor.

Use in Children (6-17 years old):

The recommended dose is 2.5 mg to 5 mg once daily.

Overdose:

If you think you have taken too much of GD-amlodipine contact your doctor, nurse, pharmacist, hospital emergency department or regional Poison control Centre immediately, even if there are no symptoms.

One or more of the following signs may occur in an overdose:

Low blood pressure and rapid heartbeat.

Missed Dose:

If you miss a dose, take it as soon as you remember. If it has been more than 12 hours since you missed your last dose, skip the missed dose and continue with the next dose at your regular time. Do not take double doses.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Side effects include:

- Headaches
- Tiredness, extreme sleepiness
- Stomach pain, nausea
- Dizziness

If any of these affects you severely, tell your doctor, nurse or pharmacist.

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

Symptom / effect		Talk with your doctor, nurse or pharmacist		Stop taking drug and seek immediate emergency medical help
		Only if severe	In all cases	
Common	Flushing : Hot or warm feeling in your face	Y		
	Edema: Swelling of your legs or ankles	Y		
Uncommon	Arrhythmia: Rapid, slow or irregular heartbeat		Y	

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

Symptom / effect	Talk with your doctor, nurse or pharmacist		Stop taking drug and seek
Increased frequency, severity, duration of angina: Pressing or squeezing pain in your chest		Y	
Heart Attack: Pain, fullness and/or squeezing of the chest, jaw pain and/or arm pain, shortness of breath			Y
Liver Disorders: Yellowing of the skin or eye, dark urine, abdominal pain, nausea, vomiting, loss of appetite		Y	
Allergic reactions: Rash, hives, swelling of the face, lips, tongue or throat, difficulty breathing or swallowing			Y
Low Blood Pressure: Dizziness, fainting, lightheadedness May occur when you go from lying or sitting to standing up	Y		

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

Symptom / effect		Talk with your doctor, nurse or pharmacist		Stop taking drug and seek
Unknown	Extrapyramidal symptoms: Muscle stiffness, body spasms, upward eye rolling, exaggeration of reflexes, drooling, difficulty moving how and when you want.			Y

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

HOW TO STORE IT

Keep GD-amlodipine out of the reach and sight of children. Store GD-amlodipine Tablets at room temperature (between 15-30°C). Protect GD-amlodipine from light.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: **Canada Vigilance Program
Health Canada
Postal Locator-1908C
Ottawa, Ontario
K1A 0K9**

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at:
<http://www.pfizer.ca>
 or by contacting the sponsor, GenMed, a division of Pfizer Canada Inc., at: 1-800-463-6001

This leaflet was prepared by GenMed, a division of Pfizer Canada Inc.

Last revised: October 23, 2017