

PART III: CONSUMER INFORMATION

Pr MYLAN-NIFEDIPINE EXTENDED RELEASE

Nifedipine Extended Release Tablets

20 mg, 30 mg and 60 mg

USP

This leaflet is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about MYLAN-NIFEDIPINE EXTENDED RELEASE. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

MYLAN-NIFEDIPINE EXTENDED RELEASE is used for:

Chronic Stable Angina

MYLAN-NIFEDIPINE EXTENDED RELEASE may be used in patients to manage chronic stable angina.

High Blood Pressure

MYLAN-NIFEDIPINE EXTENDED RELEASE may be used in patients to manage mild to moderate high blood pressure.

What it does:

MYLAN-NIFEDIPINE EXTENDED RELEASE manages high blood pressure and chronic stable angina. It is called a “calcium channel blocker”. Although the mechanism by which MYLAN-NIFEDIPINE EXTENDED RELEASE reduces blood pressure and relieves angina is not fully known, it is believed to be brought about as a result of the ability of MYLAN-NIFEDIPINE EXTENDED RELEASE to widen and relax blood vessels.

When it should not be used:

You should not use MYLAN-NIFEDIPINE EXTENDED RELEASE if you:

- are allergic to nifedipine, or to any of the nonmedicinal ingredients

- have allergies to other drugs that are similar to MYLAN-NIFEDIPINE EXTENDED RELEASE (dihydropyridines calcium antagonists)
- are pregnant, breastfeeding, or a woman of childbearing age
- have severe low blood pressure or are in shock
- are taking the medicine rifampicin
- have a Kock pouch (a pouch or reservoir created inside the abdomen with a portion of large bowel for which a tube or catheter can be inserted through the abdominal wall to drain the reservoir)
- have moderate to severe liver disease
- have severe narrowing in your stomach or intestines

What the medicinal ingredient is:

Nifedipine.

What the non-medicinal ingredients are:

20 mg: cellulose acetate, colloidal silicon dioxide, FD&C Blue #1, hydroxypropylcellulose, hydroxypropyl methylcellulose, iron oxide black, iron oxide red, magnesium stearate, polydextrose, polyethylene glycol, polyethylene oxide, propylene glycolsodium chloride, sodium stearyl fumarate and titanium dioxide.

30 mg and 60 mg: Cellulose acetate, colloidal silicon dioxide, glycerol triacetate, hydroxypropyl methylcellulose, iron oxide black, iron oxide red, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyethylene oxide, polysorbate, povidone, propylene glycol, sodium chloride and titanium dioxide.

What dosage forms it comes in:

The medication in MYLAN-NIFEDIPINE EXTENDED RELEASE is packed within a nonabsorbable shell that has been specially designed to slowly release the drug at a constant rate over time so that the body can absorb it. The shell will pass into your stool after your body has absorbed the medicine. This is normal and is nothing to worry about.

MYLAN-NIFEDIPINE EXTENDED RELEASE 20 mg are available in bottles of 30 tablets and 100 tablets and cartons with blisters of 30 tablets (3x10's).

MYLAN-NIFEDIPINE EXTENDED RELEASE 30 mg and 60 mg are available in bottles of 100 tablets and cartons with blisters of 30 tablets (2x15's).

WARNINGS AND PRECAUTIONS

Before you use MYLAN-NIFEDIPINE EXTENDED RELEASE, talk to your doctor or pharmacist if you:

- are pregnant or breastfeeding
- have heart failure, liver disease, kidney disease, or coronary artery disease
- have unstable angina (sudden chest pain that occurs at rest and gets increasingly worse)
- have recently had a heart attack or you have a heart condition called aortic stenosis (narrowing of a valve in your heart)
- have pre-existing gastrointestinal narrowing disease
- have diabetes
- have a history of poor blood circulation in the brain.
- are scheduled for surgery with a general anaesthetic
- are a man and have been repeatedly unsuccessful at fathering a child by in vitro fertilization

Driving and using machines: Before you perform tasks which may require special attention, wait until you know how you respond to MYLAN-NIFEDIPINE EXTENDED RELEASE. Your ability to drive or to operate machinery may be impaired particularly at the start of treatment, when changing the medication, or in combination with alcohol.

INTERACTIONS WITH THIS MEDICATION

As with most medicines, interactions with other drugs are possible. Tell your healthcare professional about all the medicines you take, including drugs prescribed by other doctors, vitamins, minerals, natural supplements, or alternative medicines.

The following may interact with MYLAN-NIFEDIPINE EXTENDED RELEASE:

Drug-Drug Interactions

- azole antifungals (ketoconazole, itraconazole or fluconazole)
- cyclosporine

- carbamazepine
- cimetidine, ranitidine
- diltiazem
- digoxin
- erythromycin, clarithromycin
- fluoxetine
- HIV protease inhibitors (indinavir, nelfinavir, ritonavir, saquinavir, or amprenavir)
- nefazodone
- phenobarbital
- phenytoin
- quinidine
- quinupristin/dalfopristin
- tacrolimus
- rifampicin
- valproic acid
- blood pressure lowering drugs including beta blockers
- benzodiazepines
- cisapride
- coumarin anticoagulants
- warfarin
- imipramine
- propafenone
- terfenadine

Drug-Food Interactions

DO NOT eat grapefruit or drink grapefruit juice while you are using this medicine.

Drug-Herb Interactions

Saint John's Wort

PROPER USE OF THIS MEDICATION

You must swallow MYLAN-NIFEDIPINE EXTENDED RELEASE tablets whole. Do not bite, chew, divide or crush the tablets. This can result in a large immediate release of the drug.

You can take this medication with or without food.

Your doctor will tell you how much of this medicine to use and how often. Your dose may need to be changed several times in order to find out what works best for you. Follow your doctor's treatment plan exactly so that you reach and maintain your blood pressure targets, and get relief from angina. Do not use more medicine or use it more often than your doctor tells you to.

IMPORTANT: PLEASE READ

Do not discontinue a medication on your own. If you have a problem with a drug, always tell your doctor.

Dosage should be individualised.

Usual dose:

Doses greater than 90 mg a day are not recommended.

Chronic Stable Angina

- Starting Dose: 30 mg once a day

High Blood Pressure

- Starting Dose: 20 mg to 30 mg once a day
- Usual Maintenance Dose: 30 to 60 mg once a day.

Overdose

If you think you have taken too much MYLAN-NIFEDIPINE EXTENDED RELEASE, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose

If you miss a dose or forget to use your medicine, use it as soon as you can. If it is almost time for your next dose, wait until then to use the medicine and skip the missed dose. Do not use extra medicine to make up for a missed dose unless instructed by your doctor.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Side effects may include:

- headaches, anxiety, numbness and/or pins and needles (hypoesthesia), confusion, insomnia, nervousness, weakness, excessive muscle movement
- dizziness, fatigue
- nausea, upset stomach, indigestion, dry mouth
- enlargement of the gums
- muscle or joint pain, leg cramps, back pain
- rash, itch, sensitivity to the sun

- impotence, breast enlargement in men, menstrual disorder for women
- abnormally large production of urine, the need to urinate at night, lack of urine or incontinence
- eye pain

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

MYLAN-NIFEDIPINE EXTENDED RELEASE can cause abnormal blood test results. Your doctor will decide when to perform blood tests and will interpret the results.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN 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	Wheezing or trouble breathing			√
	Angina Pectoris: chest tightness, chest pain			√
	Edema: swelling of tissues of the hands, ankles, feet or legs	√		
	Abdominal cramps		√	
	Vomiting		√	
	Diarrhea		√	
	Irregular heartbeat			√
	Fast heartbeat			√
Uncommon	Constipation		√	
	Allergic Reactions: difficulty breathing or swallowing, rash or hives (redness, intense itching and burning), swelling of the face, throat,			√

IMPORTANT: PLEASE READ

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN 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	
	tongue, lips, eyes, hands, feet, ankles, or lower legs			
	Low Blood Pressure: dizziness, fainting, lightheadedness		√	
Unknown	Liver Disorder (hepatitis and cholestasis): yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite		√	
	Myocardial Infarction: heart attack			√
	Toxic Epidermal Necrolysis: severe skin peeling, especially in the mouth and eyes			√
	Intestinal (bowel) Obstruction: swollen, hard or painful abdomen, vomiting, and constipation/no stools.			√

MYLAN-NIFEDIPINE EXTENDED RELEASE 20 mg, 30 mg and 60 mg should be stored between 15°C and 30°C. Protect from light, humidity and moisture.

Keep out of reach and sight of children.

Never share your medicine with anyone.

Ask your healthcare professional about the best way to dispose of any outdated medicine or medicine no longer needed.

This is not a complete list of side effects. For any unexpected side effects while taking MYLAN-NIFEDIPINE EXTENDED RELEASE, contact your doctor or pharmacist.

HOW TO STORE IT

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.html) (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.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

This document can be found at: www.mylan.ca.

The full Product Monograph prepared for health professionals can be obtained by contacting the sponsor, Mylan Pharmaceuticals ULC, Etobicoke, Ontario M8Z 2S6.

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