

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PRO-NIFEDIPINE ER

Nifedipine Extended-Release Tablets

Read this carefully before you start taking **PRO-NIFEDIPINE ER** 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 **PRO-NIFEDIPINE ER**.

What is PRO-NIFEDIPINE ER used for?

PRO-NIFEDIPINE ER is used in adults to control:

- chest pain that most often occurs with physical activity or emotional stress (chronic stable angina). It can be used with other chest pain medicines when those medicines do not provide enough benefit on their own. PRO-NIFEDIPINE ER is normally used in patients who have tried beta blockers and/or nitrates for their chest pain, but did not receive benefits, or had bad side effects.
- mild to moderate high blood pressure.

How does PRO-NIFEDIPINE ER work?

PRO-NIFEDIPINE ER belongs to the group of medicines called “calcium channel blockers” or “calcium antagonists”. It works by:

- relaxing and expanding the blood vessels. This makes the blood flow more easily and lowers blood pressure. Lower blood pressure reduces the strain on your heart.
- relaxing and expanding the arteries supplying the heart. This allows more blood and oxygen to reach the heart and decreases the strain on it. Your angina attacks (chest pain) will be less severe and less frequent if there is less strain on the heart.

What are the ingredients in PRO-NIFEDIPINE ER?

Medicinal ingredients: Nifedipine

Non-medicinal ingredients: Black iron oxide, Cellulose Acetate, Ferric Oxide, Hypromellose, Magnesium Stearate, Polyethylene Glycol, Polyethylene Oxide, Potassium Chloride, Povidone K-30, Sodium Chloride, Titanium Dioxide.

PRO-NIFEDIPINE ER comes in the following dosage forms:

Extended-release tablets: 30 mg

Do not use PRO-NIFEDIPINE ER if:

- you are allergic to nifedipine or any of the other ingredients in PRO-NIFEDIPINE ER.
- you are allergic to medicines that are similar to PRO-NIFEDIPINE ER (i.e., dihydropyridines calcium antagonists) such as amlodipine, clevidipine, felodipine, isradipine, and nimodipine.
- you have very low blood pressure.

- you are going into cardiogenic shock (your heart suddenly cannot pump enough blood and oxygen to the brain and other vital organs).
- you are pregnant or plan to become pregnant.
- you are a woman of childbearing potential, unless you and your healthcare professional have decided you should take PRO-NIFEDIPINE ER.
- you are breastfeeding or plan to breastfeed.
- you are taking rifampicin (used to treat bacterial infections, including tuberculosis).
- you have a Kock pouch (a pouch or reservoir created inside the abdomen with a portion of the small intestines for which a tube or catheter can be inserted through the abdominal wall to drain the reservoir).
- you have moderate to severe liver disease.
- you have severe intestinal obstruction (blockage that stops or impairs the passage of contents through the intestines).

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

- have mild liver disease.
- have diabetes.
- have very high blood pressure that comes on suddenly and quickly.
- have a history of or are prone to low blood pressure.
- have a history of poor blood circulation in the brain.
- have had or will have surgery under general anaesthesia.
- had a recent heart attack.
- have a severe heart condition such as heart failure or aortic stenosis (narrowing of a valve in your heart).
- have obstructive coronary artery disease (gradual narrowing or closing of arteries that supply the heart with blood due to plaque buildup).
- have severe narrowing of the intestines, or an inflammatory bowel disease such as Crohn's disease, or a history of intestinal or esophageal obstruction (blockage that stops or impairs the passage of contents through the intestines or esophagus).
- have unstable angina (sudden chest pain that occurs at rest and gets increasingly worse).
- have angina (chest pain) and recently stopped taking beta blockers (medicines used to treat high blood pressure and other circulatory problems). You may experience withdrawal symptoms, including increased chest pain. Starting treatment with PRO-NIFEDIPINE ER may not prevent these withdrawal symptoms and may even make them worse.
- are a man and are planning or currently trying to father a child by in vitro fertilization.

Other warnings you should know about:

PRO-NIFEDIPINE ER can cause serious side effects, including:

- **Hypotension** (low blood pressure): This can occur after your first dose or after your dose is increased. Your risk may be greater if you also take beta blockers (medicines used to treat high blood pressure or other circulatory problems). Tell your healthcare professional if you

experience excessive symptoms of low blood pressure, including fainting. They may adjust your dose or stop your treatment with PRO-NIFEDIPINE ER altogether.

- **Angina pectoris** (chest pain) and **Myocardial infarction** (heart attack): In rare cases, PRO-NIFEDIPINE ER can cause chest pain that is new or worse after your first dose or after your dose is increased. Heart attack can also occur. The risk is greater if you have severe heart disease. If you experience chest pain, stop taking PRO-NIFEDIPINE ER and seek medical help **right away**.
- **Intestinal obstruction** (blockage that stops or impairs passage of contents through the intestines): The outer shell of PRO-NIFEDIPINE ER tablets does not dissolve in the intestines. Although rare, this may increase your risk of intestinal obstruction, especially if you have or have had severe bowel problems. If you experience symptoms of intestinal obstruction, stop taking PRO-NIFEDIPINE ER and seek medical help **right away**. In some cases, surgery may be required.

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

Diabetes: If you have diabetes, PRO-NIFEDIPINE ER may affect your blood sugar control. Closely monitor your blood sugar while taking PRO-NIFEDIPINE ER. Tell your healthcare professional if you notice that you have difficulty controlling your blood sugar levels during your treatment. They may adjust your dose of PRO-NIFEDIPINE ER.

Fertility (male): PRO-NIFEDIPINE ER may affect your chance to father a child. Talk to your healthcare professional if this is important to you.

Driving and using machines: PRO-NIFEDIPINE ER can decrease your blood pressure causing lightheadedness, dizziness and fainting. These can occur more often after your first dose, when your dose is increased, or in combination with alcohol. Before you drive or do tasks that require special attention, wait until you know how you respond to PRO-NIFEDIPINE ER.

Check-ups and testing: You will have regular visits with your healthcare professional while you are taking PRO-NIFEDIPINE ER to monitor your blood pressure and heart rate. If you have mild liver disease, they may also do blood tests to monitor the health of your liver during treatment.

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 PRO-NIFEDIPINE ER if:

- you are taking rifampicin (used to treat bacterial infections, including tuberculosis) as you may have serious side effects.

The following may also interact with PRO-NIFEDIPINE ER:

- other medicines used to treat high blood pressure and/or chest pain, including calcium channel blockers (e.g., amlodipine, clevidipine, felodipine, isradipine, nimodipine, diltiazem) and beta blockers (e.g., atenolol, metoprolol, labetalol, propranolol)
- medicines used to treat seizures (e.g., phenobarbital, phenytoin, valproic acid, carbamazepine)
- medicines used to treat fungal infections with a name ending in “azole” (e.g., ketoconazole, itraconazole, fluconazole)
- medicines used to treat bacterial infections (e.g., erythromycin, clarithromycin, quinupristin/dalfopristin). Taking clarithromycin with PRO-NIFEDIPINE ER may increase your risk of kidney problems if you are elderly.
- medicines used to suppress the immune system (e.g., tacrolimus, cyclosporine)
- medicines used to treat depression (e.g., imipramine, fluoxetine, nefazodone)
- medicines used to treat HIV/AIDS (e.g., amprenavir, indinavir, nelfinavir, ritonavir, saquinavir)
- medicines used to treat an irregular heartbeat (e.g., propafenone, quinidine)
- medicines used to treat ulcers of the stomach and intestines (e.g., cimetidine, ranitidine)
- benzodiazepines, used to treat anxiety, seizures and insomnia
- terfenadine, used to treat allergies
- warfarin, used to treat or prevent blood clots
- digoxin, used to treat various heart conditions
- theophylline, used to treat asthma and other lung diseases
- St. John’s Wort, a herbal remedy
- grapefruit or grapefruit juice. Do not eat grapefruit or drink grapefruit juice while taking PRO-NIFEDIPINE ER.
- alcohol

How to take PRO-NIFEDIPINE ER:

- Take PRO-NIFEDIPINE ER exactly as directed by your healthcare professional.
- **You must swallow PRO-NIFEDIPINE ER tablets whole. DO NOT bite, chew, divide or crush the tablets. Doing so can release all of the medicine at once, increasing the risk of side effects.**
- Do not change your dose or stop taking PRO-NIFEDIPINE ER without talking with your healthcare professional first.
- Never share your medicine with anyone.

Usual dose:

The dose of PRO-NIFEDIPINE ER prescribed to you will depend on your condition.

- **To treat chest pain (chronic stable angina):** The usual starting dose is 30 mg once a day.
- **To treat high blood pressure:** The usual starting dose is 20 mg* to 30 mg once a day. The usual maintenance dose is 30 mg to 60 mg* once a day.

Your healthcare professional may slowly increase your dose (over 7 to 14 days) to find the dose that works best for you. Follow their instructions carefully.

The maximum daily dose is 90 mg.

* Note: PRO-NIFEDIPINE ER is only marketed in the 30 mg strength.

Overdose:

Signs of an overdose with PRO-NIFEDIPINE ER may include:

- low blood pressure that can lead to shock (rapid breathing, pale skin cold and sweaty skin). It can be accompanied with a buildup of fluids in the lungs (difficulty breathing, especially while lying down).
- high blood sugar (increased thirst, dry mouth, needing to pee frequently).
- buildup of acid in the body (confusion, rapid heartbeat, feeling sick, headache, long and deep breaths).
- low levels of oxygen in your body tissues (shortness of breath, headache, confusion or restlessness).
- slow or rapid heartbeat.
- decreased consciousness or coma.

If you think you, or a person you are caring for, have taken too much PRO-NIFEDIPINE ER, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you have forgotten or missed a dose, take it as soon as you remember. However, if it is almost time for your next dose, skip the missed dose and take your next dose at the usual time. Do not double the doses.

What are the possible side effects from using PRO-NIFEDIPINE ER?

These are not all the possible side effects you may have when taking PRO-NIFEDIPINE ER. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- headaches, anxiety, loss of sensation in a body part, burning or prickling sensation in the hands, arms, legs or feet, 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 healthcare professional.

PRO-NIFEDIPINE ER 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	
COMMON			
Wheezing or trouble breathing			✓
Angina pectoris (not enough oxygen to the heart muscle): pain or pressure in the chest, discomfort in the shoulder, arms, back, throat jaw or teeth.			✓
Edema: swelling of the hands, ankles, feet or legs	✓		
Abdominal cramps		✓	
Vomiting		✓	
Diarrhea		✓	
Irregular or fast heartbeat			✓
UNCOMMON			
Constipation		✓	
Allergic reaction/Angioedema: difficulty breathing or swallowing, rash or hives (redness, intense itching and burning), swelling of the face, throat, tongue, lips, eyes, hands, feet, ankles, or lower legs			✓
Hypotension (low blood pressure): dizziness, fainting, lightheadedness, blurred vision, nausea, vomiting, fatigue (may occur when you go from lying or sitting to standing up)		✓	
UNKNOWN FREQUENCY			
Liver disorder (including hepatitis and cholestasis): yellowing of the skin or eyes		✓	

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	
(jaundice), dark urine, pale stools, abdominal pain, nausea, vomiting, loss of appetite			
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.			✓
Toxic Epidermal Necrolysis (TEN) : (severe skin reaction): redness, blistering and/or peeling of large areas of the skin, especially in the mouth and eyes			✓
Intestinal obstruction (blockage that stops or impairs passage of contents of intestines): cramping pain in abdomen that may begin suddenly, bloating, loss of appetite, pain that comes and goes but will then last, nausea and vomiting, constipation or diarrhea			✓

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 at room temperature (15°C to 30°C). Protect from light and humidity.
- Keep out of reach and sight of children
- Ask your healthcare professional about the best way to dispose of any expired medicine or medicine no longer needed.

If you want more information about PRO-NIFEDIPINE ER:

- 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>), or by contacting Pro Doc Ltee : 1-800-361-8559, www.prodoc.qc.ca, medinfo@prodoc.qc.ca

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