

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr PRO-DILTIAZEM CD

Diltiazem Hydrochloride Controlled Delivery Capsules

Read this carefully before you start taking **PRO-DILTIAZEM CD** 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-DILTIAZEM CD**.

What is PRO-DILTIAZEM CD used for?

PRO-DILTIAZEM CD 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-DILTIAZEM CD is normally used in patients who have tried other treatments for their chest pain, but did not receive benefits, or had bad side effects.
- treat mild to moderate high blood pressure.

What does PRO-DILTIAZEM CD work?

PRO-DILTIAZEM CD belongs to a group of medicines called “calcium channel blockers” or “calcium antagonists”. It works by:

- relaxing the arteries, which allows blood to flow freely through them. This helps to lower blood pressure.
- reducing the amount of oxygen that your heart muscle needs. This helps to control chest pain.

What are the ingredients in PRO-DILTIAZEM CD?

Medicinal ingredients: Diltiazem Hydrochloride.

Non-medicinal ingredients: Eudragit, FD&C blue #1, gelatin, iron oxide black (300 mg only) methacrylic acid copolymer, methylcellulose, microcrystalline cellulose, polysorbate 80, talc, titanium dioxide and tributyl citrate.

PRO-DILTIAZEM CD comes in the following dosage forms:

Controlled-delivery capsules: 120 mg, 180 mg, 240 mg, and 300 mg

Do not use PRO-DILTIAZEM CD if:

- you are allergic to diltiazem or any other ingredients in PRO-DILTIAZEM CD or its container.
- you have any heart rhythm disorders and do not have a pacemaker.
- you have very low blood pressure (less than 90 mmHg systolic).
- you have a very slow heartbeat (less than 40 beats/minute).
- you have had a heart attack and have fluid in your lungs as a result of heart failure.
- you are pregnant or plan to become pregnant.
- you are a woman of child-bearing potential, unless you and your healthcare professional have decided you should take PRO-DILTIAZEM CD.
- you are breastfeeding or planning to breastfeed.
- you are taking the following medicines:
 - dantrolene, used to treat severe muscle spasms or severe fever;
 - ivabradine, used to treat heart failure;
 - lomitapide mesylate, used to treat high blood cholesterol.

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

- have heart, liver or kidney disease.
- had a recent heart attack.
- have a history of heart failure.
- are at risk of developing an intestinal obstruction (blockage).
- have asthma or other breathing problems. PRO-DILTIAZEM CD may cause your symptoms to get worse, especially after a dose increase.
- have high blood sugar or diabetes.
- are 65 years of age or older.

Other warnings you should know about:

PRO-DILTIAZEM CD can cause serious side effects, including:

- **Kidney problems:** PRO-DILTIAZEM CD can cause kidney problems, even at prescribed doses. You are at higher risk if you have heart failure, a very slow heartbeat or very low blood pressure.
- **Hyperglycemia** (high blood sugar): PRO-DILTIAZEM CD may affect your blood sugar. If you have diabetes, closely monitor your blood sugar while taking PRO-DILTIAZEM CD and report any unusual results to your healthcare professional.

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

Surgery: Tell any doctor, dentist, pharmacist or healthcare professional that you see, that you are taking this medicine. This is especially important if you are planning to have surgery (including dental procedures).

Pregnancy:

- Avoid becoming pregnant while you are taking PRO-DILTIAZEM CD. If you are able to get pregnant, you should use effective birth control (contraception) during your treatment. Talk to your healthcare professional about the best kind of birth control to use while you are taking PRO-DILTIAZEM CD.
- If you take PRO-DILTIAZEM CD during pregnancy, it may harm your unborn baby. Your healthcare professional will discuss the risks with you.
- If you discover that you are pregnant, stop taking PRO-DILTIAZEM CD and tell your healthcare professional right away.

Breastfeeding: PRO-DILTIAZEM CD passes into breast milk and may harm your baby. Do not breastfeed during treatment with PRO-DILTIAZEM CD. Talk to your healthcare professional about ways to feed your baby during this time.

Adults (65 years of age or older): Side effects like swelling of the arms or legs, irregular heartbeat, dizziness, skin rash and frequent urination may happen more often. Your healthcare professional might adjust your dose of PRO-DILTIAZEM CD. They will monitor your health during and after treatment.

Checks-up and testing:

- You will have regular visits with your healthcare professional while you are taking PRO-DILTIAZEM CD to monitor your health. They will:
 - do blood and urine tests to check your liver and kidney health, and the level of sugar in your blood;
 - check your lungs and verify if you have any breathing problems.
- PRO-DILTIAZEM CD can cause abnormal blood test results. Your healthcare professional 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.

Serious Drug Interactions

Do not take PRO-DILTIAZEM CD with:

- dantrolene, used to treat severe muscle spasms or severe fever;
- ivabradine, used to treat heart failure;
- lomitapide mesylate, used to treat high blood cholesterol.

Taking PRO-DILTIAZEM CD with any of these medicines may cause serious drug interactions. Ask your healthcare professional if you are unsure you are taking these medicines.

The following may also interact with PRO-DILTIAZEM CD:

- medications used to treat fungal infection with a name ending in “azole”;
- medicines used to treat bacterial infections, such as rifampin, erythromycin, clarithromycin;
- medicines used to treat high blood pressure, such as alpha antagonists, beta blockers;
- heart medications, such as amiodarone, digoxin, digitalis, flecainide, nifedipine, propafenone, quinidine, verapamil;
- medicines used to treat chest pain (angina), such as short or long acting nitrates;
- medicines used to control seizures, such as carbamazepine, phenytoin, phenobarbital;
- medicines used to lower blood cholesterol, such as “statins”;
- medicines used to reduce stomach acid and treat ulcers in the stomach or intestines, such as cimetidine, ranitidine;
- medicines used to treat inflammation, such as corticosteroids (including methylprednisolone);
- acetylsalicylic acid (ASA, or ASPIRIN) or medicines used to prevent blood clots, such as ticagrelor, cilostazol, clopidogrel, dipyridamole, ticlopidine, warfarin;
- sleeping pills, such as benzodiazepines (midazolam, triazolam);
- anesthetics;
- cyclosporine, used to control the immune system;
- lithium, used to treat bipolar disorder;
- imipramine, used to treat depression;
- theophylline, used to treat asthma or other lung diseases;
- terfenadine, used to treat allergies;
- ritonavir, used to treat HIV/AIDS;
- products that contain calcium such as multivitamins with minerals;
- X-ray contrast agents.

Alcohol

Drinking alcohol while taking PRO-DILTIAZEM CD may cause low blood pressure and dizziness when you go from lying or sitting to standing up. This is more likely to occur after the first dose or when the dose is increased. Tell your healthcare professional if you experience dizziness, light-headedness, fainting, decreased blood pressure or increased heart rate.

Grapefruit juice

Drinking grapefruit juice while taking PRO-DILTIAZEM CD may cause headache, irregular heartbeat, edema (swelling), unexplained weight gain, and chest pain. Tell your healthcare professional if this happens to you. Your healthcare professional may recommend that you avoid grapefruit juice while taking PRO-DILTIAZEM CD.

How to take PRO-DILTIAZEM CD:

- Your dose is tailored/personalized just for you. Take PRO-DILTIAZEM CD exactly as your healthcare professional tells you.
- PRO-DILTIAZEM CD is taken once a day.
- Swallow capsules whole. Do not chew or crush capsules.
- Do not increase or decrease your dose without consulting your healthcare professional. Taking higher doses can lead to more side effects and a greater chance of overdose.

Usual Dose:

To control chest pain:

- **Usual starting dose:** 120 mg to 180 mg once a day.
- Your dose may be slowly (over 7 to 14 days) increased up to 360 mg once a day. Follow your healthcare professional's instructions carefully.

To treat high blood pressure:

- **Usual starting dose:** 180 mg to 240 mg once a day. 120 mg a day may be used in some patients.
- **Maximum dose:** 360 mg a day.

Overdose:

Signs of an overdose with PRO-DILTIAZEM CD include:

- very slow or irregular heartbeat.
- very low blood pressure.
- kidney problems.
- heart does not pump blood as well as it should or suddenly stops beating.

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

Missed Dose:

If you miss 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 as scheduled. Do not take two doses at once to make-up for a missed dose.

What are possible side effects from using PRO-DILTIAZEM CD?

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

Side effects may include:

- Headache, dizziness, malaise;
- Nausea (feeling like vomiting);
- Flushing (facial redness) or feeling unusually warm;
- Unusual tiredness and weakness;
- Upset stomach or indigestion.

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			
Allergic reaction: rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			√
Fast, slow or irregular heartbeat		√	
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).	√		
Peripheral edema: (swelling of the legs or hands): swollen or puffy legs, ankles or hands, feeling heavy, achy or stiff	√		

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	
Respiratory tract infection: (a cold): runny or stuffy nose, sore throat, cough, sinus congestion, body aches, headache, sneezing, fever, generally feeling unwell		√	
UNCOMMON			
Angina (chest pain): discomfort in the shoulder, arm, back, throat, jaw or teeth; pain or pressure in the chest		√	
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	√		
Eye problems: blurred vision, loss of vision in the eye, increased sensitivity of the eyes to light, eye pain or redness, swelling and itching of the eyelids	√		
Heart block (a disease in the electrical system of the heart): light-headedness, fainting, irregular heartbeat			√

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	
Heart failure (heart does not pump blood as well as it should): shortness of breath, fatigue and weakness, leg swelling in legs, ankles and feet, cough, lack of appetite, nausea, rapid or irregular heartbeat, reduced ability to exercise		√	
Hyperglycemia: (high blood sugar): increased thirst and hunger, frequent urination, thirst, and hunger headache, blurred vision, fatigue	√		
RARE			
Kidney problems: nausea, vomiting, fever, swelling of extremities, fatigue, thirst, dry skin, irritability, dark urine, increased or decreased urine output, blood in the urine, rash, weight gain (from retaining fluid), loss of appetite, abnormal blood test results, mental status changes (drowsiness, confusion, coma)		√	
Liver problems: yellowing of the skin or eyes, dark urine, stomach pain or swelling, nausea, vomiting, unusual tiredness		√	
Severe skin reactions: fever, severe rash, swollen lymph glands, flu-like feeling, blisters and peeling skin that may start in and around			√

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	
the mouth, nose, eyes and genitals and spread to other areas of the body, yellow skin or eyes, shortness of breath, dry cough, chest pain or discomfort, feeling thirsty, urinating less often, less urine			

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.
- Keep out of reach and sight of children.

If you want more information about PRO-DILTIAZEM CD:

- 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 Ltée at: 1-800-361-8559, www.prodoc.qc.ca or medinfo@prodoc.qc.ca

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