

PART III: CONSUMER INFORMATION

Pr DILTIAZEM TZ
Diltiazem hydrochloride
Extended-release Capsules

Read this carefully before you start taking DILTIAZEM TZ and each time you get a refill. This leaflet is a summary and will not tell you everything about Diltiazem TZ. Talk to your doctor, nurse, or pharmacist about your medical condition and treatment and ask if there is any new information about Diltiazem TZ.

ABOUT THIS MEDICATION**What the medication is used for:**

DILTIAZEM TZ is used for:

- the management of effort associated **angina** (chest pain)
- the treatment of mild to moderate **high blood pressure**.

DILTIAZEM TZ should normally be used in those patients in whom treatment with other blood pressure reduction medications has been ineffective, or have been associated with unacceptable side effects.

What it does:

DILTIAZEM TZ belongs to the group of drugs called “calcium channel blockers” or “calcium antagonists”. DILTIAZEM TZ relaxes the arteries, thereby lowering blood pressure.

DILTIAZEM TZ reduces the amount of oxygen that your heart muscle needs. This helps control chest pain.

When it should not be used:

Do not use DILTIAZEM TZ if:

- You are pregnant or plan to become pregnant.
- You are breastfeeding.
- You have a known allergy to diltiazem or to any of the non-medicinal ingredients.
- You have very low blood pressure (< 90 mmHg systolic).
- You have heart rhythm disorders in the absence of a pacemaker.
- You have severe heart failure with fluid in the lungs.
- You are taking a medicine called dantrolene used for severe muscle spasms or severe fever.
- You are using ivabradine.

What the medicinal ingredient is:

Diltiazem Hydrochloride

What the nonmedicinal ingredients are:

Ethylcellulose, gelatin, hydroxypropyl methylcellulose, magnesium stearate, polymethacrylate, polysorbate, povidone, sugarspheres, talc and titanium dioxide.

DILTIAZEM TZ also contains the following:

120 mg: D&C red #28, FD&C blue #1

180 mg: black iron oxide, FD&C green #3

240 mg: D&C Green #3, D&C red #28, FD&C blue #1

300 mg: black iron oxide, D&C red #28, FD&C blue #1

360 mg: Green #3

What dosage forms it comes in:

Capsules: 120 mg, 180 mg, 240 mg, 300 mg and 360 mg.

WARNINGS AND PRECAUTIONS**BEFORE you use DILTIAZEM TZ talk to your doctor or pharmacist if:**

- You have a known allergy to diltiazem or to any of the non-medicinal ingredients in Diltiazem TZ.
- You have very low blood pressure.
- You have ever had a bad or unusual reaction to any drug containing diltiazem in the past.
- You have heart, liver, or kidney disease.
- You had a recent heart attack.
- You have high blood sugar or diabetes.
- You are 65 years or older.

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.

Additional monitoring of your dose or condition may be needed if you are taking other drugs.

The following may interact with Diltiazem TZ:

- Antifungal medications with a name ending in azole;
- Medications used to control the immune systems such as cyclosporine;
- Certain antibiotics should not be taken with DILTIAZEM TZ such as erythromycin, rifampin. Check with your pharmacist if you are not sure;
- Sleeping pills such as benzodiazepines (midazolam, triazolam);
- Other blood pressure medications: alpha antagonists, beta-blockers;
- Heart medications: Amiodarone, digoxin, digitalis, flecainide, nifedipine, propafenone, quinidine, verapamil, ivabradine;
- Anaesthetics;
- Lithium and imipramine used for some types of mental illness;
- Drugs that dilate the blood vessels: short and long acting nitrates; Medications used to control seizures: carbamazepine, phenobarbital, phenytoin;
- Warfarin used as anticoagulant;
- Cholesterol lowering medications: statins;
- Theophylline used for breathing problems;
- Terfenadine or ranitidine used for allergies;
- Medications used to control stomach ulcers such as cimetidine will increase the effects of Diltiazem TZ;
- Multivitamins with minerals (calcium-containing products);
- Drugs to treat inflammation: corticosteroids, methylprednisolone;
- Dantrolene used for severe muscle spasms or severe fever.
- Acetylsalicylic acid (Aspirin) or antiplatelet drugs.

- X-ray contrast agents.

Alcohol may cause low blood pressure and dizziness when you go from lying or sitting to standing up. This can especially occur after the first dose and when the dose is increased. Tell your doctor if you experience dizziness, light-headedness, fainting, decreased blood pressure or increased heart rate.

Grapefruit juice when consumed too often while taking DILTIAZEM TZ may cause headache, irregular heartbeat, edema (swelling), unexplained weight gain, and chest pain. Tell your doctor if this happens to you. Your doctor may recommend that grapefruit juice be avoided if this happens to you.

PROPER USE OF THIS MEDICATION

- Do not miss doses or take extra doses, unless your doctor tells you. If you are not clear about the directions, ask your doctor or pharmacist.

Take DILTIAZEM TZ exactly as your doctor tells you. DILTIAZEM TZ is taken once a day at about the same time every day

DO NOT chew or crush DILTIAZEM TZ capsules.

Usual Adult Dose:

High blood pressure

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

Angina

Dosage should be individualised.
Starting dose: 120 mg to 180 mg once a day.
Dose may be slowly (over 7 to 14 days) increased up to 360 mg a day. Always follow your doctor's instructions.

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If a dose of this medication has been missed, it should be taken as soon as possible. However, if it is almost time for the next dose, skip the missed dose and go back to the regular dosing schedule.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Side effects may include:

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

DILTIAZEM TZ can cause abnormal blood 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 with your doctor, nurse or pharmacist		Stop taking drug and seek immediate medical help
		Only if severe	In all cases	
Common	Low Blood Pressure: dizziness, fainting, light-headedness May occur when you go from lying or sitting to standing up.	✓		
	Fast, slow, or irregular heartbeat		✓	
	Peripheral edema: swelling of the ankles	✓		
	Respiratory tract infection: pharyngitis, rhinitis		✓	
	Allergic Reaction: rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			✓
Uncommon	Depression: low mood, lack of interest in usual activities, change in sleep and appetite.	✓		
	Heart block: A disease in the electrical system of the heart causing lightheadedness, fainting and irregular heartbeat.			✓
	Heart Attack: shortness of breath, chest pain			✓
	Angina: Chest pain		✓	
	Heart Failure: shortness of breath, leg swelling, and exercise		✓	

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 medical help
	Only if severe	In all cases	
intolerance.			
Eye Problems: decreased vision, irritation, sore red eyes	✓		
Increased blood sugar: frequent urination, thirst, and hunger	✓		
Rare		✓	
Unknown			✓
	Serious Skin Reactions (Stevens-Johnson Syndrome, Toxic Epidermal Necrolysis, hypersensitivity Syndrome): any combination of itchy skin rash, redness, blistering and peeling of the skin and /or of the lips, eyes, mouth, nasal passages or genitals, accompanied by fever, chills, headache, cough, body aches or joint pain, yellowing of the skin or eyes, dark urine.		

This is not a complete list of side effects. For any unexpected effects while taking Diltiazem TZ, contact your doctor or pharmacist.

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 0701E
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 by contacting Pro Doc Ltée at 1-800-361-8559, www.prodoc.qc.ca or info@prodoc.qc.ca.

This leaflet was prepared by Pro Doc Ltée, Laval, Québec, H7L 3W9

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HOW TO STORE IT

Store in tight containers between 15 and 30°C. Protect from light. **Keep out of sight and reach of children.**