

**READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION**

Pr CARVEDILOL

Carvedilol Tablets

3.125 mg, 6.25 mg, 12.5 mg and 25 mg

Read this carefully before you start taking CARVEDILOL 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 CARVEDILOL.

What is CARVEDILOL used for?

CARVEDILOL is used to treat heart failure in adults.

How does CARVEDILOL work?

CARVEDILOL works by relaxing and widening your blood vessels. This makes it easier for your heart to pump blood around your body. This helps reduce your blood pressure and the strain on your heart.

What are the ingredients in CARVEDILOL?

What the medicinal ingredient is:

Carvedilol

What the important nonmedicinal ingredients are:

Core tablet contains:

Lactose Monohydrate (Pharmatose 200M) (Lactochem® Fine power), Silica, Colloidal Anhydrous (Aerosil 200), Crospovidone (Type A) (Polyplasdone XL), Povidone (Kollidon 30), Sucrose (60/200), Crospovidone (Type B) (Polyplasdone XL-10), Magnesium Stearate.

Coating contains:

Polyethylene Glycol 400 (Polyglycol 400), Polysorbate 80 (Tween 80), Titanium Dioxide, Hypromellose (Methocel E5 LV Premium).

CARVEDILOL comes in the following dosage forms:

CARVEDILOL is available as 3.125 mg, 6.25 mg, 12.5 mg and 25 mg tablets.

Do not use CARVEDILOL if:

- Your doctor did not prescribe it for you
- You are allergic to carvedilol or any of the other ingredients in CARVEDILOL
- You have severe heart failure that requires you to be in the hospital for treatment
- You have asthma, wheezing, bronchitis or other breathing problems
- You have an abnormal heart beat and do not have a permanent pacemaker in place
- You have severe heart damage and your heart is not able to pump enough blood to meet your body's needs
- You have very low blood pressure
- You have a very slow heart beat
- You have heart valve problems (primary obstructive valvular disease)
- You have severe liver disease
- You have problems making decisions (for example, if you have dementia, alcohol or drug problems). Do not use CARVEDILOL unless you are being cared for by an appropriate caregiver.
- Have one of the following rare hereditary diseases:
 - Galactose intolerance
 - Lapp lactase deficiency
 - Glucose-galactose malabsorption
- If you are 18 years or younger

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

- Have a history of heart problems or disease
- Have or had kidney or liver problems
- Have low blood pressure
- Are pregnant or thinking of becoming pregnant
- Are breastfeeding
- Have diabetes. You could become less aware of the symptoms of hyperglycemia (high blood sugar) and you should monitor your blood sugar levels more carefully.
- Have thyroid problems
- Have Raynaud's syndrome. CARVEDILOL may increase the symptoms of coldness and/or spasms in your hands and feet or cramping pains in the legs when exercising.
- Have psoriasis (scaly red patches on your skin)
- Have problems with blood flow to your feet and legs (peripheral artery disease). CARVEDILOL can make your symptoms worse.
- Have a condition called pheochromocytoma (a tumour of the adrenal gland)
- Have allergic reactions or allergies
- Are having a planned surgery and will be given an anesthetic
- Wear contact lenses. You may suffer from eye dryness while using CARVEDILOL.

Other warnings you should know about:

Pregnancy: CARVEDILOL is not usually recommended for use during pregnancy. Your doctor will consider the benefit to you versus the risk to your unborn baby.

Breastfeeding: CARVEDILOL can pass into breast milk. Do not use CARVEDILOL if you are breastfeeding.

Driving and using machines: Before doing tasks that require special attention, wait until you know how you respond to CARVEDILOL.

Do not drink alcohol while taking CARVEDILOL.

You should have regular eye exams while taking CARVEDILOL.

Tell your health professional if you notice that your heart failure symptoms are getting worse, like an increase in shortness of breath, tiredness, dizziness, or swelling of the ankles. This may occur when your dose is increased and may indicate that your dose needs to be changed.

Do not stop taking CARVEDILOL all of a sudden. Under the care of your healthcare professional, it should be stopped slowly over 2 weeks.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with CARVEDILOL:

- Alcohol
- Antidepressants used in the treatment of depression and mood disorders
- Antidiabetic drugs including insulin and oral medications
- Blood pressure drugs such as clonidine
- Cyclosporine used after organ transplants
- Digoxin, a heart medication
- Drugs used to treat stomach acid or heartburn (such as cimetidine)
- Drugs used to treat hypertension and irregular heartbeat (such as diltiazem and verapamil)
- Fingolimod, a medicine used to treat multiple sclerosis
- Grapefruit juice
- MAO inhibitors such as selegiline (Parkinson's Disease), tranylcypromine (depression)
- Nitroglycerin used to treat chest pain
- Rifampin used to treat tuberculosis
- Warfarin used to prevent blood clots

How to take CARVEDILOL:

Swallow the tablet **whole** with water. **DO NOT** chew, crush or break the tablet. Take CARVEDILOL:

- exactly as prescribed
- every day
- twice a day, at about the same time every day
- with food

Usual adult dose:

Starting dose: 3.125 mg twice a day for 2 weeks Maximum daily dose: 25 mg twice a day

Your doctor may start you on a different dose or change your dose over time depending on how CARVEDILOL works for you.

Do not stop taking CARVEDILOL without consulting your doctor. This can be dangerous.

Overdose:

If you think you, or a person you are caring for, have taken too much CARVEDILOL, 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. You can take your next dose at the normal time, but do **NOT** take 2 doses within 6 hours of each other.

If you miss more than 2 doses of CARVEDILOL, contact your healthcare professional. Do **NOT** restart taking CARVEDILOL until you have spoken to your healthcare professional

What are possible side effects from using CARVEDILOL?

These are not all possible side effects you may feel when taking CARVEDILOL. If you experience any side effects not listed here, contact your healthcare professional. Please also see Warnings and Precautions.

Side effects may include:

- headache

- trouble sleeping
- drowsiness
- weakness
- cough, stuffy and runny nose
- rash, itching
- abdominal pain, diarrhea, indigestion, nausea, vomiting
- back pain

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	
Breathing problems: trouble breathing, wheezing, shortness of breath and stuffy nose		√	
COMMON			
Allergic Reactions: rashes, hot or itching skin			√
Blurred vision		√	
Chest pain		√	
Constipation		√	
Diarrhea		√	
Dizziness when standing up		√	
Fainting (passing out)		√	
Headache		√	
Impotence (in men): trouble getting or keeping an erection		√	
Pain in the side including passing urine more or less frequently		√	
Sleep disturbance: problems falling or staying asleep		√	
Slowing of the heart rate		√	
Nausea and vomiting		√	
Swelling		√	
Weight gain		√	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to 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.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)

If you want more information about CARVEDILOL:

- 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 calling at 1-855-788-3153.

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