

PART III: CONSUMER INFORMATION**Pr CARVEDILOL
(carvedilol tablets)**

This leaflet is part III of a three-part “Product Monograph” published when **CARVEDILOL** (carvedilol) was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about **CARVEDILOL**. Contact your doctor or pharmacist if you have any questions about the drug.

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

- **CARVEDILOL** is used in the treatment of heart failure.
- **CARVEDILOL** has been prescribed to you by your doctor to help manage your symptoms of heart failure.

What it does:

CARVEDILOL helps the heart to work more effectively in heart failure by blocking the action of certain hormones on the heart and blood vessels and reducing the resistance that the heart has to pump against.

When it should not be used:

- Do not use **CARVEDILOL** if you are allergic to it or any of the components of its formulation (see *What the important non medicinal ingredients are*).
- You should not take **CARVEDILOL** if you have any of the following health problems:
- Severe heart failure that requires treatment with certain medications (usually given in the hospital)
- Asthma, wheezing, bronchitis or other breathing problems
- Certain types of abnormal heart beat (i.e., second- or third- degree AV block, or sick sinus syndrome) unless treated with a heart pacemaker
- Shock, caused by weakened heart
- Very low blood pressure
- Very slow heart beat
- Certain heart valve problems (i.e., primary obstructive valvular heart disease)
- Liver disease
- Inability to make decisions (for example, if you have dementia, alcohol or drugs problems), unless closely supervised by an appropriate caregiver

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).

What dosage forms it comes in:

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

WARNINGS AND PRECAUTIONS

If you become unwell while taking **CARVEDILOL** tell your doctor at once. You should be especially careful when starting or changing the dose of **CARVEDILOL**.

BEFORE and while you use **CARVEDILOL** tell your doctor or pharmacist:

- all your medical conditions, including a history of heart, kidney or liver problems, asthma or breathing difficulties;
- if you are pregnant or thinking of becoming pregnant, or if you are breast feeding. You should not take **CARVEDILOL** if you are pregnant or if you plan to become pregnant unless your doctor tells you so;
- if you change the amount of any other medicine you are taking;
- if you suffer from diabetes, thyroid problems, Raynaud's phenomenon (coldness/spasm in the hands or feet with changes in colour) or cramping pains in the leg when exercising:
 - if you have diabetes, you could become less aware of symptoms of hypoglycaemia (low blood sugar). You should monitor your blood sugar more carefully while on **CARVEDILOL**. Tell your doctor if you see any significant changes;
 - if you have certain types of thyroid problem, abrupt stopping of **CARVEDILOL** may lead to worsening symptoms;

IMPORTANT: PLEASE READ

- if you suffer from Raynaud's phenomenon, an increase in symptoms of coldness/spasms in the hands or feet may be seen;
- if you suffer have psoriasis (scaly red patches on the skin). Psoriasis may occur or, if you already have psoriasis, it may become worse

If you see another physician other than your heart doctor for another condition, tell this physician that you are taking **CARVEDILOL**.

INTERACTIONS WITH THIS MEDICATION

- **CARVEDILOL** should not be taken with alcohol.
- Taking **CARVEDILOL** with certain medications (prescription or non prescription), especially antihypertensives, digoxin, insulin, hypoglycemics, stomach medication, tricyclic antidepressants, stomach medication, tricyclic antidepressants, clonidine, and rifampin, may cause unintended effects and you should discuss the possibilities with your doctor.

PROPER USE OF THIS MEDICATION

- **It is very important that you take CARVEDILOL exactly as your doctor has instructed.** The doctor will decide how many tablets you need to take each day, when and for how long. It may be necessary for the doctor to increase or decrease the dose.
- You should swallow the tablets whole with water. Do not chew or break your tablet.
- Take your tablets at the same time each day. You should take **CARVEDILOL** with food.

Do **not** stop taking **CARVEDILOL** without first consulting with your doctor.

- **Remember: This medicine is for the person named by the doctor. Do not give it to anybody else.**

Overdose:

If you have taken more tablets than the recommended dose, tell your doctor or the nearest hospital emergency department immediately. Show the doctor your bottle of tablets and any other medications you are taking.

Missed Dose:

Take it as soon as you remember. If possible, 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 doctor. Do not re-start **CARVEDILOL** until you have spoken to the doctor.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

- Some people may have unwanted effects when taking **CARVEDILOL**. Dizziness, headache and tiredness are the most common and often occur when **CARVEDILOL** is started or when the dose of **CARVEDILOL** is changed. These symptoms generally go away with continued use. If they do not or appear to become more severe then tell your doctor.
- If you experience dizziness or fatigue while taking your tablets, do not drive or operate machinery.
- Other possible effects are: stomach complaints such as diarrhea, constipation, nausea and vomiting, allergic reactions such as rashes and hot or itching skin, pain in the side, urinating more or less frequently, breathing problems such as wheezing, breathlessness and stuffy nose, depressed mood, sleep disturbance, dry mouth, slowing of heart rate, dizziness when standing up, fainting, cold or painful hands and feet, general swelling of parts of the body, weight gain, impotence, blurred vision, cramping pain on exercise.
- If you develop any unusual discomfort, tell the doctor as soon as possible, especially if you have unusual dizziness, ankle swelling, tiredness or breathlessness when you start use **CARVEDILOL** or when your dose is being increased.
- If you wear contact lenses you may suffer from dryness of the eyes while taking your tablets.

IMPORTANT: PLEASE READ

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist, seek medical help immediately
		Only if severe	In all cases	
Very Common	Dizziness and /or headache	√		
Common	Low blood pressure (symptoms of low blood pressure include dizziness, lightheadedness and/or feeling faint)	√		
Common	Fluid retention or swelling		√	
Common	Usually slow heartbeat		√	
Common	Breathing problems (such as wheezing, shortness of breath)		√	
Uncommon	Vision abnormalities		√	
Uncommon	Fainting		√	
Uncommon	Feeling of irregular heart beat		√	
Rare	Kidney problems including urinating more or less frequently than normal	√		
Very rare	Allergic reactions (sudden wheezing, chest tightness, swelling of the eyelids face or lips, lumpy skin rash or hives)			√

HOW TO STORE IT

Store at room temperature (15°C to 30°C).

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, ON 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

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://health-products.canada.ca/dpd-bdpp> ; the manufacturer's website www.sivem.ca , or by calling 1-855-788-3135

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