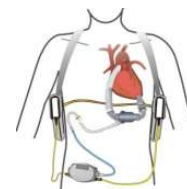
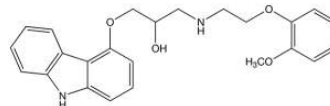


Rx CARVEDILOL

(Carvedilol is used for treating high blood pressure and congestive heart failure)



GENERIC NAME: carvedilol

DRUG CLASS AND MECHANISM

Carvedilol is used for treating high blood pressure and congestive heart failure. It is related to labetalol (Normodyne, Trandate). Carvedilol blocks receptors of the adrenergic nervous system, the system of nerves in which epinephrine (adrenalin) is active. Nerves from the adrenergic system enter the heart and release an adrenergic chemical (norepinephrine) that attaches to receptors on the heart's muscle and stimulates the muscle to beat more rapidly and forcefully. By blocking the receptors, carvedilol reduces the heart's rate and force of contraction and thereby reduces the work of the heart. Carvedilol also blocks adrenergic receptors on arteries and causes the arteries to relax and the blood pressure to fall. The drop in blood pressure further reduces the work of the heart since it is easier to pump blood against a lower pressure. The FDA first approved carvedilol in 1995.

GENERIC AVAILABLE: yes

PRESCRIPTION: yes

PREPARATION: Tablets, 3.125mg, 6.25mg, 12.5mg, and 25mg.

PRESCRIBED FOR

Carvedilol is used by itself or with a diuretic ("water-pill") to control high blood pressure. Carvedilol also may be used in combination with other drugs to manage mild or moderate congestive heart failure. When combined with other treatments for heart disease among patients with recent heart attacks, carvedilol can reduce the risk of a second heart attack by 40% and increase survival among patients with congestive heart failure.

DOSING

Carvedilol usually is given twice daily. For high blood pressure, the dose may range from 6.25mg twice daily to a maximum of 25mg twice daily. For congestive heart failure, the dose may range from 3.25mg twice daily to a maximum of 25mg twice daily in persons weighing less than 85kg (187 pounds) or 50mg twice daily in persons weighing more than 85kg (187 pounds). Carvedilol should be taken with food since this increases the amount of absorbed drug that reaches the heart and arteries. Stopping and changing doses of carvedilol should be done under the direction of a physician since sudden changes in dose can result in serious cardiac complications such as arrhythmias.

DRUG INTERACTIONS

Carvedilol can mask early warning symptoms of hypoglycemia (low blood sugar) such as tremors and increased heart rate. (These symptoms are caused by activation of the adrenergic nervous system which is blocked by the carvedilol.) Therefore, patients with diabetes taking medications that lower blood sugar such as insulin or oral anti-diabetic medications may need to increase the frequency with which they monitor their blood sugar.

Carvedilol taken with calcium channel blockers such as diltiazem (Cardizem) or verapamil (Calan) may trigger an irregular heart rhythm or an increase in blood pressure.

Reserpine, monoamine oxidase inhibitors (phenelzine or isocarboxazid) and clonidine (Catapres), because they have similar mechanisms of action as carvedilol, may greatly accentuate the effects of carvedilol and cause a steep decline in blood pressure and/or heart rate. Close monitoring of blood pressure and heart rate may be needed.

Carvedilol may cause an increase in digoxin (Lanoxin) blood levels. Therefore, in patients receiving digoxin, the digoxin blood level should be monitored if carvedilol is started, adjusted or discontinued.

Rifampin (Rifadin) can sharply decrease the carvedilol blood level. Therefore, in patients taking rifampin, the dose of carvedilol may need to be increased.

Carvedilol shares a common pathway for elimination by the liver with several other drugs such as quinidine (Quinaglute), fluoxetine (Prozac), paroxetine (Paxil), or propafenone (Rythmol). Use of these drugs may block the elimination of carvedilol. No studies have been done to confirm these effects on the elimination of carvedilol; however, carvedilol blood levels may be increased (along with the risk for carvedilol's side effects) if patients are taking any of these drugs.

Carvedilol may increase the levels in the blood of cyclosporin (Sandimmune,

Neoral), and the dose cyclosporin may need to be adjusted when the two drugs are used together.

Amiodarone (Cordarone) may increase carvedilol levels in the blood, increasing the effects and potential for toxicity of carvedilol.

USES

This medication is an alpha and beta blocker used to treat high blood pressure and heart failure. It is also used after a heart attack to improve the chance of survival. Lowering high blood pressure helps prevent strokes, heart attacks, and kidney problems. This drug works by blocking the action of certain natural chemicals in your body (such as epinephrine) that affect the heart and blood vessels. This effect lowers heart rate, blood pressure, and strain on the heart.

HOW TO USE

See also Warning section. Read the Patient Information Leaflet provided by your pharmacist before you start using carvedilol and each time you get a refill. If you have any questions, consult your doctor or pharmacist. Take this medication by mouth with food, usually twice daily or as directed by your doctor. Dosage is based on your medical condition and response to treatment. Use this medication regularly to get the most benefit from it. To help you remember, take it at the same times each day. Do not suddenly stop taking this medication without consulting your doctor. Your condition may become worse when the drug is suddenly stopped. Your dose should be gradually decreased. For the treatment of high blood pressure, it may take 1 to 2 weeks before you get the full benefit of this drug. It is important to continue taking this medication even if you feel well. Most people with high blood pressure do not feel sick. Tell your doctor if your condition worsens (e.g., your routine blood pressure readings increase).

SIDE EFFECTS

See also Warning and Precautions sections. Dizziness, lightheadedness, drowsiness, diarrhea, or tiredness may occur. If any of these effects persist or worsen, tell your doctor or pharmacist promptly. To lower your risk of dizziness and lightheadedness, get up slowly when rising from a sitting or lying position. The risk of dizziness is highest within 1 hour after you take your dose. Dizziness is most common when you first start using this drug or any time your doctor increases your dose. This drug may reduce blood flow to your hands and feet, causing them to feel cold. Smoking may worsen this effect. Dress warmly and avoid tobacco use. Remember that your doctor has prescribed this medication because he or she has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects. Tell your doctor immediately if any of these unlikely but serious side effects occur: very slow heartbeat, severe dizziness, fainting, unusual weakness, new or increased shortness of breath, sudden weight gain, swelling hands/ankles/feet, increased thirst/urination, numbness/tingling of the hands/feet, bluish fingers/toes. Tell your doctor immediately if any of these rare but very serious side effects occur: change in the amount of urine, easy bruising/bleeding, mental/mood changes (e.g., depression, nervousness), seizures. A very serious allergic reaction to this drug is rare. However, seek immediate medical attention if you notice any symptoms of a serious allergic reaction, including: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing. This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist. In the US - Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. In Canada - Call your doctor for medical advice about side effects. You may report side effects to Health Canada at 1-866-234-2345.

PRECAUTIONS

Before taking carvedilol, tell your doctor or pharmacist if you are allergic to it; or if you have had a serious reaction to other beta blockers (e.g., propranolol); or if you have any other allergies. This medication should not be used if you have certain medical conditions. Before using this medicine, consult your doctor or pharmacist if you have: asthma, certain types of heart rhythm problems (sinus bradycardia, sick sinus syndrome, second- or third-degree atrioventricular block), severe heart failure. Before using this medication, tell your doctor or pharmacist your medical history, especially of: liver disease, serious reaction/allergy needing treatment with epinephrine, other breathing problems (e.g., bronchitis, emphysema), other heart problems (e.g., Prinzmetal's variant angina), diabetes, overactive thyroid disease (hyperthyroidism), kidney disease, blood circulation problems (e.g., Raynaud's disease, peripheral vascular disease), a certain type of tumor (pheochromocytoma), mental/mood disorders (e.g., depression), a certain muscle disease (myasthenia gravis). Before having surgery, tell your doctor or dentist that you are taking this medication. This drug may make you dizzy or drowsy or cause you to faint. This is most likely to occur within 1 hour after taking your dose or any time your doctor

increases your dose. Do not drive, use machinery, or do any activity that requires alertness until you are sure you can perform such activities safely. Limit alcoholic beverages. If you have diabetes, this product may prevent the fast/pounding heartbeat you would usually feel when your blood sugar level falls too low (hypoglycemia). Other symptoms of a low blood sugar level, such as dizziness and sweating, are unaffected by this drug. This product also may make it harder to control your blood sugar levels. Check your blood sugar levels regularly as directed by your doctor. Tell your doctor immediately if you have symptoms of high blood sugar such as increased thirst, hunger, and urination. Your anti-diabetic medication or diet may need to be adjusted. Caution is advised when using this drug in older adults because they may be more sensitive to its effects, especially dizziness and lightheadedness. During pregnancy, this medication should be used only when clearly needed. Discuss the risks and benefits with your doctor. Based on information from related drugs, this medication may pass into breast milk and may have undesirable effects on a nursing infant. Consult your doctor before breast-feeding.

OVERDOSE

If overdose is suspected, contact your local poison control center or emergency room immediately. US residents can call the US National Poison Hotline at 1-800-222-1222. Canada residents can call a provincial poison control center. Symptoms of overdose may include: very slow heartbeat, severe dizziness, fainting, slow/shallow breathing, seizures.

MISSED DOSE

If you miss a dose, use it as soon as you remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up.

STORAGE

Store at room temperature away from light and moisture. Different brands/strengths of this medication may have different storage requirements. Read the package labeling or ask your pharmacist for the storage requirements for the product you are using. Protect from light. Do not store in the bathroom. Keep all medicines away from children and pets. Do not flush medications down the toilet or pour them into a drain unless instructed to do so. Properly discard this product when it is expired or no longer needed. Consult your pharmacist or local waste disposal company for more details about how to safely discard your product. **MEDICAL ALERT:** Your condition can cause complications in a medical emergency. For information about enrolling in MedicAlert, call 1-800-854-1166 (USA) or 1-800-668-1507 (Canada).

WARNING: Do not stop using this drug without first consulting your doctor. Your condition may become worse when the drug is suddenly stopped, especially if you have chest pain (angina) or heart disease (e.g., coronary artery disease, ischemic heart disease, heart failure, high blood pressure). If your doctor decides you should no longer use this drug, you must gradually decrease your dose according to your doctor's instructions.

When gradually stopping this medication, it is recommended that you temporarily limit physical activity to decrease strain on the heart. Seek immediate medical attention if you develop: worsening chest pain, tightness/pressure in the chest, chest pain spreading to the jaw/neck/arm, unusual sweating, trouble breathing, or fast/irregular heartbeat.

Note : This product information is intended only for residents of the India. Taj Pharmaceuticals Limited, medicines help to treat and prevent a range of conditions—from the most common to the most challenging—for people around the world.



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Revised November 2010