Taj Pharmaceuticals Ltd.

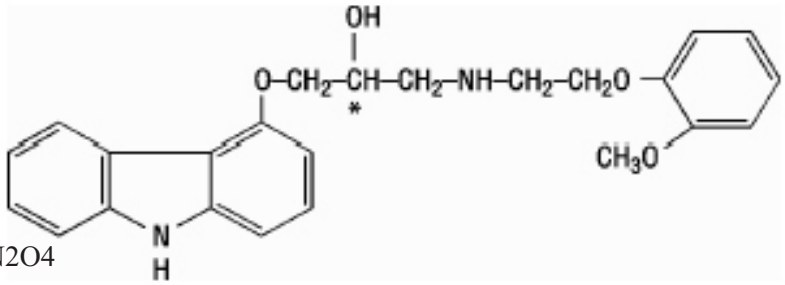
Carvedilol

CAS No. : 72956-09-3

CAS No [72956-09-3]

Chemical Name

1-(9H-Clarbazol-4-yloxy)-3-[[2-(2-methoxyphenoxy)ethyl[amino]-2-propanol
BM-14190
DQ-2466
Coreg
Dilatrend
Dimitone
Eucardic
Kredex
Querto



Molecular Formula C24H26N2O4 / C24H26N2O4
Molecular Weight 406.47
Therapeutic Category Anihypertensive; in treatment of congestive heart failure.

DOSAGE

The starting dosage of carvedilol is 3.125 mg orally twice daily for two weeks. This dosage is the same regardless of the patient's age or weight. Because food slows the rate (but not the extent) of absorption, carvedilol should be taken with food to reduce the incidence of orthostatic hypotension. Patients should be observed in the physician's office for adverse reactions, especially dizziness, lightheadedness and hypotension, for one hour after the first dose and again after each dosage increase. Blood pressure should be measured with the patient standing. Patients should be instructed to weigh themselves every day and to contact their physician immediately if they experience a weight gain of 0.91 to 1.36 kg (2 to 3 lb) above their usual "dry" weight. If, after two weeks, the initial dosage of carvedilol has been well-tolerated, it should be doubled. The dosage should be doubled every two weeks to the maximum dosage or the highest tolerated dosage. The maximum recommended dosage for carvedilol is 25 mg twice daily in patients weighing less than 85 kg (187 lb) and 50 mg twice daily in patients weighing 85 kg (187 lb) or more Recommendations for the administration and titration of carvedilol are summarized in Tables 3 and 4.It may also be necessary, based on clinical signs and symptoms, to adjust the dosages of the patient's other heart failure medications when carvedilol is introduced. When patients have signs and symptoms of excessive vasodilation, such as dizziness, lightheadedness or orthostatic hypotension, consideration should be given to decreasing diuretic, vasodilator or ACE inhibitor dosages. If these signs and symptoms persist, the dosage of carvedilol should be decreased. In patients with signs and symptoms of worsening heart failure, such as edema, weight gain or dyspnea, the dosage of diuretic therapy should be increased. If evidence of worsening heart failure persists, the dosage of carvedilol should be decreased. In patients with bradycardia or first-degree atrioventricular block, carvedilol should be titrated to maintain a heart rate greater than 55 beats per minute. Finally, patients should be advised not to stop taking carvedilol abruptly or without a physician's advice. When carvedilol therapy must be discontinued, the drug should be tapered slowly over seven to 14 days

SIDE EFFECTS

As with any medicine, side effects are possible with carvedilolHowever, not everyone who takes the medicine will experience side effects. In fact, most people tolerate it quite well. If side effects do occur, they are generally minor and either require no treatment or can easily be treated by you or a healthcare provider. Serious side effects are less common.

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Carvedilol has been studied extensively in people with high blood pressure, congestive heart failure, and recent heart attack. In these studies, the side effects that occurred in a group of people taking the drug were documented and then compared to the side effects that occurred in another group of people taking a placebo (a "sugar pill" that does not contain any active ingredients). As a result, it was possible to see what side effects occurred, how often they appeared, and how they compared to the group not taking the medicine.

Other common side effects of carvedilol (occurring in more than 3 percent of people with congestive heart failure or those following a heart attack) include but are not limited to:

* Swelling of the arms, legs, hands, or feet
* Shortness of breath
* Vomiting
* Fainting (syncope)
* Changes in vision
* Anemia.

High Blood Pressure
The most common carvedilol side effects seen in people with high blood pressure include:

* Dizziness -- up to 6 percent
* Insomnia -- up to 2 percent
* Slow heart rate -- up to 2 percent
* Drop in blood pressure when standing from either a sitting or lying down position -- up to 2 percent
* Diarrhea -- up to 2 percent.

Side effects tend to get worse with increasing doses.
Serious Side Effects of Carvedilol
Some carvedilol side effects should be reported immediately to your healthcare provider. These potentially serious side effects include but are not limited to:

* Unexplained skin rash
* Itching
* Wheezing
* Difficulty breathing or swallowing
* Unexplained swelling or sudden weight gain
* Chest pain
* Dizziness, lightheadedness, or fainting spells
* Sweating, shaking, or extreme hunger
* Confusion
* Irregular heartbeat.

DRUG DESCRIPTION

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

Carvedilol is a beta blocker and an alpha blocker:Norepinephrine stimulates the nerves that control the muscles of the heart by binding to the β1- and β2-adrenergic receptors. Carvedilol blocks the binding to those receptorswhich both slows the heart rhythm and reduces the force of the heart's pumping. This lowers blood pressure and reduces heart failure.Norepinephrine also binds to the a1-adrenergic receptors on blood vessels, causing them to constrict and raise blood pressure. Carvedilol blocks this binding to the a1-adrenergic receptors toowhich also lowers blood pressure.Relative to other beta blockers, carvedilol has minimal inverse agonist activityThis suggests that carvedilol has a reduced negative chronotropic and inotropic effect compared to other beta blockers, which may decrease its potential to worsen symptoms of heart failure. However, to date this theoretical benefit has not been established in clinical trials, and the current version of the ACC/AHA guidelines on congestive heart failure management does not give preference to carvedilol over other beta-blockers

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The Controlled Substances Act (CSA) was enacted into law by the Congress of the United States as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970.[1] The CSA is the federal U.S. drug policy under which the manufacture, importation, possession, use and distribution of certain substances is regulated. The Act also served as the national implementing legislation for the Single Convention on Narcotic Drugs

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91 022 30601000.
This leaflet was prepared by
Taj Pharmaceuticals Limited,
Mumbai (India).
MPSTJ278
Last revised: 29 August 2009