Carvista®

Carvedilol Tablet

Presentation

Carvista® 3.125 : Each film coated tablet contains Carvedilol BP 3.125 mg.
Carvista® 6.25 : Each film coated tablet contains Carvedilol BP 6.25 mg.
Carvista® 12.5 : Each film coated tablet contains Carvedilol BP 12.5 mg.
Carvista® 25 : Each film coated tablet contains Carvedilol BP 25 mg.

Description

Carvista (Carvedilol) is a cardiovascular drug whose main pharmacological action is non-selective antagonism of β-adrenergic receptors but which also possesses appreciable α-adrenergic antagonistic activity. It also has antiproliferative properties and is a scavenger of reactive free oxidant radicals. It is used in the treatment of hypertension, angina pectoris and congestive heart failure.

Indications and Use

Carvista (Carvedilol) is indicated for the treatment of mild, moderate or severe heart failure of ischemic or cardiomyopathic origin, in conjunction with digitalis, diuretics and ACE inhibitor, to reduce the progression of disease as evidenced by cardiovascular death, cardiovascular hospitalization, or the need to adjust other heart failure medications. Carvista (Carvedilol) may be used in patients unable to tolerate an ACE inhibitor. Carvista (Carvedilol) may be used in patients who are not receiving digitalis, hydralazine or nitrate therapy.

Dosage and Administration

In hypertension initially 12.5 mg once daily, increased after 2 days to usual dose of 25 mg once daily; if necessary the dose may be further increased at intervals of at least 2 weeks to maximum 50 mg daily in single or divided doses. In elderly patients the initial dose of 12.5 mg daily may provide satisfactory control.
In angina pectoris the recommended dose for initiation of therapy is 12.5 mg twice daily for the first 2 days. Thereafter, the recommended dosage is 25 mg twice daily. For elderly patients, the maximum daily dose is 50 mg daily in divided doses.
In heart failure, initially 3.125 mg twice daily (with food) may be given, dose may be increased at intervals of at least 2 weeks to 6.25 mg twice daily, then to 12.5 mg twice daily, then to 25 mg twice daily. The dose may be increased to highest dose tolerated, maximum 25 mg twice daily in patients less than 85 kg body-weight and 50 mg twice daily in patients over 85 kg.

Side-effects

Postural hypotension, dizziness, headache, fatigue, gastro-intestinal disturbances, bradycardia; occasionally diminished peripheral circulation, peripheral oedema and painful extremities, dry mouth, dry eyes, eye irritation or disturbed vision, impotence, disturbances of micturition, influenza-like symptoms, rarely angina, AV block, exacerbation of intermittent claudication or Raynaud's phenomenon, allergic skin reactions, exacerbation of psoriasis, nasal stuffiness, wheezing, depressed mood, sleep disturbances, paresthesia, heart failure, changes in liver enzymes, thrombocytopenia, leukopenia are also reported.

Contraindications

Carvedilol is contraindicated in patients with decompensated heart failure requiring intravenous inotropic therapy, bronchial asthma or related bronchospastic conditions, second or third-degree AV block, sick sinus syndrome (unless a permanent pacemaker is in place), cardiogenic shock or severe bradycardia.

Precautions

Take caution in hepatic impairment and in heart failure monitor clinical status for 2-3 hours after initiation and after increasing each dose. Before increasing dose ensure that the renal function and heart failure are not deteriorating.

Use in Pregnancy and Lactation

Carvedilol should not be used during breast-feeding, since no studies have been performed in lactating women and animal studies have shown that carvedilol is excreted in breast milk. Safety and efficacy in children have not been established with carvedilol. Carvedilol should not be used during pregnancy as no studies have been performed in this group. Animal studies have shown that carvedilol crosses the placental barrier. No information is available on safety and efficacy of Carvedilol use in neonates.

Drug Interactions

Digoxin : In normal healthy volunteers a single dose of carvedilol taken together with a single dose of digoxin resulted in significantly increased levels of digoxin 24 hour later. Patients with congestive heart failure stabilized on digoxin have been given carvedilol concomitantly without any adverse effects. Increased monitoring of digoxin is recommended when initiating, adjusting, or discontinuing the dose of carvedilol.
Rifampin : Pretreatment with rifampin resulted in a 60% decrease in Cmax and AUC.
Warfarin : Carvedilol did not alter the in vitro plasma protein binding of warfarin.
Clonidine : β-receptor antagonists potentiate the pressor reaction which may follow sudden withdrawal of treatment with clonidine although, in theory, the α-blocking action of carvedilol should modify the pressure rise.

Storage

Do not store above 30 ^{0}C. Keep away from light and out of the reach of children.

Commercial Pack

Carvista® 3.125: Each box contains 10 blister strips of 10 tablets.
Carvista® 6.25: Each box contains 10 blister strips of 10 tablets.
Carvista® 12.5: Each box contains 5 blister strips of 10 tablets.
Carvista® 25: Each box contains 3 blister strips of 10 tablets.

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