Dilgard

Carvedilol Tablet

Presentation

Dilgard 6.25 Tablet: Each film coated tablet contains 6.25 mg Carvedilol BP. Dilgard 12.50 Tablet: Each film coated tablet contains 12.50 mg Carvedilol BP. Dilgard 25 Tablet: Each film coated tablet contains 25 mg Carvedilol BP.

Indications

- Hypertension
- Angina
- Adjunct to diuretics, digoxin, or ACE inhibitors in symptomatic chronic heart failure.

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 may be further increased at intervals of at least 2 weeks to max. 50 mg daily in single or divided doses. ELDERLY initial dose of 12.5 mg daily may provide satisfactory control.

In Angina : Initially 12.5 mg twice daily, increased after 2 days to 25 mg twice daily.

In Heart failure : Initially 3.125 mg twice daily (with food), dose 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; increased to highest dose tolerated, max. 25 mg twice daily in patients with severe heart failure or body-weight less then 85 kg and 50 mg twice daily in patients over 85 kg.

Contraindications

Carvedilol is contraindicated in patients with NYHA Grade IV heart failure, second or third degree heart block, cardiogenic shock, severe bradycardia, asthma, severe hepatic dysfunction, hypersensitivity to carvedilol.

Precautions

Since carvedilol has ß-blocking activity, it should not be discontinued abruptly, particularly in patients with ischemic heart disease. Instead, it should be discontinued over 1 or 2 weeks. Before increasing dose ensure renal function and heart failure not to deteriorate.

Side Effects

Postural hypotension, dizziness, headache, fatigue, gastro-intestinal disturbances, bradycardia, peripheral oedema and painful extremities, dry mouth, dry eyes, eye irritation, impotence, disturbances of micturition, influenza-like symptoms; rarely AV block, allergic skin reactions, nasal stuffiness, depressed mood, sleep disturbances, heart failure, changes in liver enzymes, leukopenia are also reported.

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. 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 hours later. Patients with congestive heart failure stabilized on digoxin have been given carvedilol concomitantly without any adverse effects.

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.

Storage Condition

Store in cool and dry place, away from light. Keep out of the reach of children.

Commercial Pack

Dilgard 6.25 Tablet: Each box contains 3 blister packs of 10 tablets.

Dilgard 12.50 Tablet: Each box contains 3 blister packs of 10 tablets.

Dilgard 25 Tablet: Each box contains 3 blister packs of 10 tablets.

