

Dilapress®

Tablet

Description

Dilapress is a preparation of Carvedilol which is a cardiovascular drug acts mainly as neurohormonal antagonist consisting of non-selective β blockade, α_1 blockade and antioxidant properties.

Indications

Dilapress is indicated for the treatment of essential hypertension. It can be used alone or in combination with other antihypertensive agents, especially thiazide type of diuretics.

Dilapress is also indicated for the treatment of mild to moderate heart failure, to reduce the progression of disease, to reduce mortality and cardiovascular hospitalization.

Dilapress may be used in patients unable to tolerate an ACE inhibitor.

Dilapress may be used in patients who are not receiving digitalis, hydralazine or nitrate therapy.

Dosage and Administration

In essential hypertension initially 12.5 mg once daily for 2 days is recommended. Thereafter the recommended dose is 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 heart failure, initially 3.125 mg twice daily may be given for 2 weeks, 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.

In angina pectoris the recommended dose for initiation of therapy is 12.5 mg twice daily for the first 2 days. Thereafter, the recommended dose is 25 mg twice daily. For elderly patients, the maximum daily dose is 50 mg daily in divided doses.

Contraindications

Dilapress must not be used in patients with New York Heart Association (NYHA) class IV decompensated heart failure requiring intravenous inotropic support, Asthma, Chronic obstructive pulmonary disease (COPD) with a bronchospastic component, 2nd or 3rd degree AV block, Sick Sinus syndrome (unless a permanent pacemaker is in place), cardiogenic shock or severe bradycardia. Therapy is not to be initiated in severe heart failure.

Precautions

Take precaution 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.

Drug Interactions

As with other anti-hypertensive, there is a potential for pronounced hypotension during general anaesthesia.

As with other agents with β blocking activity, Carvedilol may potentiate the effect of other concomitantly administered drugs that are anti-hypertensive in action or have hypotension as part of their adverse effect profile. As with other drugs with β blocking activity, caution should be exercised in administering Class I anti-arrhythmic drugs or calcium antagonists such as Verapamil. These drugs should be administered intravenously.

Plasma Digoxin levels may be increased in patients to whom Carvedilol and Digoxin are co-administered. Increased monitoring of Digoxin levels is recommended when initiating, adjusting or discontinuing Carvedilol.

Care should be required in those receiving inducers of mixed function oxidase e.g., Rifampicin, as serum levels of Carvedilol may be reduced.

Side Effects

Side effects include dizziness, headache, fatigue, gastrointestinal disturbances, postural hypotension, peripheral oedema, bradycardia, dry mouth, dry eyes, eye irritation or disturbed vision, impotence, disturbances of micturition, and influenza like symptoms. Rarely angina, AV block, exacerbation of intermittent claudication or Raynaud's phenomenon, allergic skin reactions, nasal stuffiness, wheezing, depressed mood, sleep disturbances, paresthesia, heart failure, changes in liver enzymes, thrombocytopenia, leucopenia are reported.

Use in Special Population

Pregnancy and lactation : Carvedilol should not be used during pregnancy as no studies have been performed in this group. Carvedilol and its metabolites are excreted in breast milk. Therefore, breastfeeding is not recommended during administration of Carvedilol.

Commercial Packs

Dilapress® 6.25 Tablet : Box containing 30 tablets in 3 x 10's blister strips.
Each tablet contains Carvedilol BP 6.25 mg.

Dilapress® 12.5 Tablet : Box containing 30 tablets in 3 x 10's blister strips.
Each tablet contains Carvedilol BP 12.5 mg.

Dilapress® 25 Tablet : Box containing 30 tablets in 3 x 10's blister strips.
Each tablet contains Carvedilol BP 25 mg.