

Presentation

Cardipro ® 50 Plus Tablet - Each film-coated tablet contains Atenolol BP 50 mg + Chlorthalidone USP 25 mg

Cardipro ® 100 Plus Tablet - Each film-coated tablet contains Atenolol BP 100 mg + Chlorthalidone USP 25 mg

Pharmacology

Atenolol and Chlorthalidone have been used singly and concomitantly for the treatment of hypertension. The antihypertensive effects of these agents are additive, and studies have shown that there is no interference with bioavailability when these agents are given together in the single combination tablet. Therefore, this combination provides a convenient formulation for the concomitant administration of these two entities. In patients with more severe hypertension, Atenolol and Chlorthalidone may be administered with other antihypertensive such as vasodilators.

Atenolol

Atenolol is a beta₁-selective (cardio selective) beta-adrenergic receptor blocking agent without membrane stabilizing or intrinsic sympathomimetic (partial agonist) activities. This preferential effect is not absolute, however, and at higher doses, Atenolol inhibits beta-2-adrenoreceptors, chiefly located in the bronchial and vascular musculature.

Chlorthalidone

Chlorthalidone is a monosulfonamyl double ring system which differs chemically from thiazide diuretics in that a double ring system is incorporated in its' structure. It is an oral diuretic with prolonged action and low toxicity. The diuretic of the drug occurs within 2 hours of an oral dose. It produces diuresis with greatly increased excretion of sodium and chloride. At maximal therapeutic dosage, Chlorthalidone is approximately equal in its diuretic effect to comparable maximal therapeutic doses of benzothiadiazine diuretics. The site of action appears to be the cortical diluting segment of the ascending limb of Henle's loop of the nephron.

Indication and Use

Cardipro ® Plus is indicated in the treatment of hypertension.

Dosage & Administration

Chlorthalidone is usually given at a dose of 25 mg daily; the usual initial dose of Atenolol is 50 mg daily. Therefore, the initial dose should be one Chlorthalidone 25 + Atenolol 50 mg (Cardipro ® 50 Plus) tablet once a day. If an optimal response is not achieved, the dosage should be increased to one Chlorthalidone 25 + Atenolol 100 mg (Cardipro ® 100 Plus) tablet once a day. Dose of two tablets once daily should not be used as initial therapy in elderly patients.

Contraindications

This combination is contraindicated in patients with: sinus bradycardia; heart block greater than first degree; cardiogenic shock; overt cardiac failure anuria; hypersensitivity to this product or to sulfonamide-derived drugs.

Side effects

This combination is usually well tolerated in properly selected patients. Most adverse effects have been mild and transient. The adverse effects observed for this combination are essentially the same as those seen with the individual components.

Overdose

No specific information is available with regard to over dosage and Atenolol and Chlorthalidone in humans. Treatment should be symptomatic and supportive and directed to the removal of any unabsorbed drug by induced emesis, or administration of activated charcoal. Atenolol can be removed from the general circulation by hemodialysis. Further consideration should be given to dehydration, electrolyte imbalance and hypotension by established procedures.

Precaution

General: This combination may aggravate peripheral arterial circulatory disorders.
Electrolyte and Fluid Balance Status: Periodic determination of serum electrolytes to detect possible electrolyte imbalance should be performed at appropriate intervals. Patients should be observed for clinical signs of fluid or electrolyte imbalance; ie, hyponatremia, hypochloremic alkalosis, and hypokalemia. Serum and urine electrolyte determinations are particularly important when the patient is vomiting excessively or receiving parenteral fluids. Measurement of potassium levels is appropriate especially in elderly patients, those receiving digitalis preparations for cardiac failure, patients whose dietary intake of potassium is abnormally low, or those suffering from gastrointestinal complaints. Hypokalemia may develop especially with brisk diuresis, when severe cirrhosis is present, or during concomitant use of corticosteroids or ACTH.

Drug Interaction

Atenolol and Chlorthalidone may potentiate the action of other antihypertensive agents used concomitantly. Patients treated with Atenolol and Chlorthalidone plus a catecholamine depletor (e.g. reserpine) should be closely observed for evidence of hypotension and/or marked bradycardia which may produce vertigo, syncope or postural hypotension. Calcium channel blockers may also have an additive effect when given with Atenolol and Chlorthalidone.

Use in Pregnancy and Lactation

Pregnancy Category D.

Nursing Mothers: Atenolol is excreted in human breast milk at a ratio of 1.5 to 6.8 when compared to the concentration in plasma. Caution should be exercised when Atenolol is administered to a nursing woman. Clinically significant bradycardia has been reported in breast-fed infants. Premature infants, or infants with impaired renal function, may be more likely to develop adverse effects.

Neonates born to mothers who are receiving Atenolol at parturition or breast-feeding may be at risk for hypoglycaemia. Caution should be exercised when this combination is administered during pregnancy or to a woman who is breast-feeding.

Use in Pediatric Patients

Safety and effectiveness in pediatric patients have not been established.

Storage Condition

Store in a cool and dry place. Protected from light and moisture.

How Supplied

Cardipro ® 50 Plus Tablet - Each box contains 3x10's tablets in blister pack.

Cardipro ® 100 Plus Tablet - Each box contains 3x10's tablets in blister pack.