

DIPLOR

AMLODIPIN BESILATE BP

Compositions:

Diplor-5 Tablet: Each tablet contains Amlodipine besilate BP equivalent to 5 mg Amlodipine.

Diplor-10 Tablet: Each tablet contains Amlodipine besylate BP equivalent to 10 mg Amlodipine.

Pharmacology:

Diplor (Amlodipine) is a dihydropyridine calcium channel blocker, with a longer duration of action, used for the treatment of hypertension and angina pectoris. Administration of Diplor(Amlodipine) results primarily in vasodilation, with reduced peripheral resistance, blood pressure and afterload, increased coronary blood flow and a reflex increase in heart rate. This in turn results in an increase in myocardial oxygen supply and cardiac output.

Dosage And Administration:

Hypertension : Usual dose is 5 mg once daily & maximum dose is 10 mg daily. Small, fragile elderly individuals, or patients with hepatic insufficiency may be started on 2.5 mg once daily. In the treatment of hypertension it may be used alone or in combination with other antihypertensive agents. Angina Pectoris & Vasospastic Angina : The recommended dose is 5-10 mg daily, with the lower dose suggested in the elderly and in patients with hepatic insufficiency. Most patient will require 10 mg for adequate effect. Amlodipine may be used alone or in combination with other anti-anginal drugs. Co-administration with other Antihypertensive or Antianginal drugs: Amlodipine has been safely administered with thiazides, ACE inhibitors, Beta Blockers, Long acting Nitrate or Sublingual Nitroglycerin. Acute Over Dosage: In humans, experience with over dosage of Amlodipine is limited. If massive over dosage occurs, active cardiac and respiratory monitoring should be instituted. Frequent blood pressure measurements are essential.

Contraindications:

Amlodipine is contra-indicated in patients with known hypersensitivity to dihydropyridine derivatives.

Warning And Precaution:

Caution should be taken in patients with hepatic impairment, congestive heart failure, sinus node disease, aortic stenosis, beta-blocker withdrawal, during pregnancy and breast-feeding.

Side Effects:

The most common side effects are dizziness, flushing, headache, hypotension and peripheral oedema, gastrointestinal disturbance, increased the frequency of micturation, lethargy and eye pain may occur. A paradoxical increase in ischemic chest pain may occur at the start of the treatment.

Use in Pregnancy and Lactation:

Pregnancy Category C. There are no adequate and well-controlled studies of Amlodipine in pregnant women. Amlodipine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. It is not known whether Amlodipine is excreted in human milk. In the absence of this information, it is recommended that nursing be discontinued while Amlodipine is administered.

Drug Interaction:

Drug Interactions:Potentially hazardous interactions: Little or no data are available in patients with markedly impaired cardiac left ventricular function; however, as with other calcium

antagonist drugs, the combination of Amlodipine and beta-blockers should be avoided in such patients. Other Significant Interactions- Digoxin: Absence of any interaction between Amlodipine and Digoxin in healthy volunteers has been documented in a controlled clinical study. Cimetidine: An unpublished clinical study indicated no interaction between, Amlodipine and Cimetidine in healthy volunteers. Warfarin: An unpublished clinical study in healthy volunteers indicates that Amlodipine did not significantly alter the effect of Warfarin on prothrombin time. Food: Food does not alter the rate or extent of absorption of Amlodipine.

Overdosage:

In humans, experience with over dosage of Amlodipine is limited. If massive over dosage occurs, active cardiac and respiratory monitoring should be instituted. Frequent blood pressure measurements are essential.

Storage:

Store in a cool (15° - 30°C) and dry place protected from light and moisture. Keep out of the reach of children.

Packing:

Diplor 5 Tablet: Each box contains 3 x 10's tablet in Blister Pack. Diplor 10 Tablet: Each box contains 3 x 10's tablet in Blister Pack.

Manufactured By:

The IBN SINA Pharmaceutical Industry PLC.

Shafipur, Gazipur, Bangladesh.