

CARDIPIN[®]

Amlodipine Besilate BP

Description:

Cardipin[®] (Amlodipine) is dihydropyridine calcium antagonist that inhibits the transmembrane influx of calcium ion into vascular smooth muscle and cardiac muscle. **Cardipin[®]** is a peripheral arterial vasodilator that directly on vascular smooth muscle to cause a reduction in peripheral vascular resistance and reduction in blood pressure.

Indications:

1. Hypertension

Cardipin[®] is indicated for the treatment of hypertension. It may be used alone or in combination with other antihypertensive agents.

2. Chronic Stable Angina

Cardipin[®] is indicated for the treatment of chronic stable angina. **Cardipin[®]** may be used alone or in combination with other antianginal agents.

3. Vasospastic Angina (Prinzmetals or variant angina)

Cardipin[®] is indicated for the treatment of confirmed or suspected vasospastic angina.

Cardipin[®] may be used as monotherapy or in combination with other antianginal drugs.

Dosage and administration:

Cardipin[®] may be taken without regard to meal. The normal initial antihypertensive oral dose of **Cardipin[®]** is 5mg once daily with a maximum dose of 10mg once daily. Small, fragile or elderly individual patients with hepatic insufficiency may be started on 2.5mg once daily and this dose may be used when adding **Cardipin[®]** to other antihypertensive therapy. Dosage should be adjusted according to each patient's need. In general, titration should proceed over 7 to 14 days so that the physician can fully assess the patient's response to each dose level. Titration may proceed more rapidly, however if clinically warranted provided the patient is assessed frequently.

The recommended dose for chronic stable or vasospastic angina is 5-10mg, with the lower dose suggested in the elderly and in patients with hepatic insufficiency. Most patients will require 10mg for adequate effect. **Cardipin[®]** has been safely administered with thiazides, ACE inhibitors, beta-blockers, long acting nitrates and or sublingual nitroglycerin.

Contraindications:

Amlodipine is contraindicated in patients with a known sensitivity to dihydropyridines. Amlodipine should not be used in cardiogenic shock, clinically significant aortic stenosis, unstable angina (excluding Prinzmetal's angina), pregnancy and lactation.

Special warnings and precautions for use:

General: Since the vasodilation induced by Amlodipine is gradual onset acute hypotension has rarely been reported after the administration of **Cardipin[®]**. Nonetheless, caution should be exercised when administering Amlodipine with any other peripheral vasodilator particularly in patients with severe aortic stenosis. There are no data to support the use of Amlodipine alone during or within one month of a myocardial infarction. The safety and efficacy of **Cardipin[®]** in hypertensive crisis has not been established.

Use in patients with congestive heart failure: Although haemodynamic studies and a controlled trial in class II-III heart failure patients have shown that **Cardipin[®]** did not lead to clinical deterioration as measured by exercise tolerance, left ventricular ejection fraction and clinical symptomatology in general, all calcium channel blockers should be used with caution in patients with heart failure.

Beta-blocker withdrawal: **Cardipin[®]** gives no protection against the danger of abrupt beta-blocker withdrawal; any such withdrawal should be gradual reduction to the dose of beta-blocker.

Patients with hepatic failure: Since **Cardipin[®]** is extensively metabolised by the liver, and plasma elimination of half life is 56 hours in patients with impaired hepatic function, so caution should be exercised when administering **Cardipin[®]** to patients with hepatic impairment.

Drug interactions:

Cardipin[®] has been safely administered with thiazide diuretics, alpha blockers, beta-blockers, ACE inhibitors, long acting nitrates, sublingual glyceryl trinitrate, nonsteroidal anti-inflammatory drugs, antibiotics and oral hypoglycemic drugs.

Co-administration of Amlodipine with digoxin did not change serum digoxin levels or digoxin renal clearance in normal volunteers. Co-administration of cimetidine did not alter the pharmacokinetic of **Cardipin[®]**.

In healthy volunteers, co-administration of **Cardipin[®]** did not significantly alter the effect of warfarin on prothrombin time.

Food does not alter the rate or extent of absorption of **Cardipin[®]**.

Side-effects:

Cardipin[®] is well tolerated. In placebo controlled clinical trials involving patients with hypertension or angina the most commonly observed side effects were headache, edema, fatigue, nausea, flushing and dizziness. No clinically significant pattern of laboratory test abnormalities related to **Cardipin[®]** has been observed.

Use during pregnancy and lactation: Although some dihydropyridine compounds have been found to be teratogenic in animals, data in the rat and rabbit for **Cardipin[®]** provide no evidence for a teratogenic effect. There is, however, no clinical experience with **Cardipin[®]** in pregnancy, or lactation.

Overdosage:

There is no well documented experience with **Cardipin[®]** overdosage, since **Cardipin[®]** absorption is slow, gastric lavage may be worthwhile in some cases. Available data suggest that gross overdosage could result in excessive peripheral vasodilatation with subsequent marked and probably prolonged systemic hypotension. Clinically significant hypotension due to **Cardipin[®]** overdosage calls for active cardiovascular support including monitor of cardiac and respiratory function, elevation of extremities and attention to circulating fluid volume and urine output. A vasoconstrictor agent may be helpful in restoring vascular tone and blood pressure that there is no contraindication to its use. Since Amlodipine[®] is highly protein bound, dialysis is unlikely to be of benefit.

Storage:

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

Package Quantities:

Cardipin[®] 5mg Tablets: Cartons of 6 x 10's tablets in blister packs; each tablet contains Amlodipine Besilate BP equivalent to Amlodipine 5mg



Manufactured by
RENATA LIMITED
Mirpur, Dhaka, Bangladesh
® Trade Mark

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Size: 80 x 190mm