

Cab

Amlodipine

Presentation

Cab[®] 5mg tablet: Each tablet contains Amlodipine 5mg as Besilate BP.

Description

Cab[®] (Amlodipine) is a calcium channel blocker of dihydropyridine group having long duration of action and used for the treatment of hypertension and angina pectoris. Cab[®] inhibits the transmembrane influx of calcium ions cardiac and smooth muscle. The mechanism of antihypertensive action of Cab[®] is due to a direct relaxant effect on vascular smooth muscle. In angina, Cab[®] reduces total ischaemic burden by dilating peripheral arterioles and probably the main coronary arteries and coronary arteries.

After oral administration of therapeutic doses, Cab[®] is well absorbed with peak blood levels between 6-12 hours post dose. The terminal plasma elimination half-life is about 35-50 hours and is consistent with once-daily administration. Steady-state plasma levels are reached after 7-8 days.

Uses

Hypertension: Cab[®] is indicated for the first line treatment of hypertension and can be used as sole agent to control blood pressure in the majority of patients. Patients not adequately controlled on a single antihypertensive agent may benefit from the addition of Cab[®] which has been used in combination with a thiazide diuretic, beta-adrenoceptor blocking agent or an angiotensin converting inhibitor.

Chronic stable angina: Cab[®] is indicated for the first line therapy of stable angina. It may be used in combination with other antianginal drugs.

Vasospastic angina: Cab[®] is indicated where clinical presentation suggests a possible vasospastic angina.

Cab[®] may be used as monotherapy, or in combination with other antianginal drugs in patients with angina that is refractory to nitrates and / or adequate doses of beta-adrenoceptor blocking agents.

Dosage and administration

For both hypertension and angina, the recommended initial dose is 5mg Cab[®] orally once daily which may be increased to a maximum dose of 10mg depending on the patient's response. Small, fragile or elderly individuals or patients with hepatic insufficiency may be started on 2.5mg once daily dose and this dose may be used when adding Cab[®] to other antihypertensive therapy.

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.

Paediatric Use

Since there is no clinical experience in patients of less than 18 years, use in children is not currently recommended.

Contra-indications, warnings etc.

Contra-indications: Cab[®] is contra-indicated in patients with a known hypersensitivity to dihydropyridines.

Warnings and Precautions:

Use in pregnancy and lactation: There is no clinical experience with Cab® in pregnancy or lactation. Accordingly, Cab® should not be administered during pregnancy or lactation or to women of child-bearing potential unless effective contraception is used.

Driving / use of machinery: Clinical experience with Cab® indicates that is unlikely to impair a patient's ability to driver or use machinery.

Drug Interactions: Cab® has been safely administered with thiazide diuretics, beta-adrenoceptor blocking drugs, angiotensin converting enzyme inhibitors, trinitrate, non-steroidal anti-inflammatory drugs, antibiotics and oral hypoglycaemic agents.

Co-administration of Cab® with digoxin did not change serum digoxin level or digoxin renal clearance in normal volunteers. Co-administration of cimetidine did not alter the pharmacokinetics of amlodipine. In healthy volunteers, co-administration of Cab® did not significantly alter the effect of warfarin on prothrombin time.

Food- Cab® can be administered regardless of food.

Adverse effects:

Cab® is well tolerated. In placebo controlled clinical trials involving patients with hypertension or angina, the most commonly observed side effects were headache, oedema, fatigue, skin erythema, nausea, flushing and dizziness. There is evidence that these effects are more common in patients treated with doses greater than 10mg daily.

Overdosage:

There is no well documented experience with Cab® overdosage. Since Amlodipine absorption is slow, gastric lavage may be worthwhile in some cases. Gross overdosage could result in excessive peripheral vasodilation with subsequent marked and probably prolonged systemic hypotension. Clinically significant hypotension due to Cab® overdosage calls for active cardiovascular support including monitoring of cardiac and respiratory function, evaluation of extremities and attention to circulating fluid volume and urine output.

A vasoconstrictor agent may be helpful in restoring vascular tone and blood pressure provided that there is no contraindication to its use. Since amlodipine is highly protein-bound, dialysis is unlikely to be of benefit.

Pharmaceutical precautions

Store below 30°C.

Package quantities

Cab® 5mg tablet: Cartons of 50 tablets in blister.

® Registered Trade Mark



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