



## Amocal®

Amlodipine

**Description:** Amlodipine Besilate (**Amocal®**) is a dihydropyridine calcium antagonist (calcium channel blocker), with a long duration of action, used for the treatment of hypertension and angina pectoris.

**Mode of action:** **Amocal®** blocks the movement of calcium through calcium channel and thereby relaxes vascular smooth muscle and dilates coronary and peripheral arteries. Thus amlodipine lowers blood pressure and anginal pain. It has a slow rate of onset with maximum and prolonged smooth muscle relaxation effect.

**Pharmacokinetics:** After oral administration of therapeutic doses, amlodipine is well absorbed with peak blood levels between 6-12 hours post dose. Absolute bioavailability has been estimated to be between 64 and 80%. The volume of distribution is approximately 21 l/kg. In vitro studies have shown that approximately 97.5% of circulating amlodipine is bound to plasma proteins.

**Biotransformation/elimination:** The terminal plasma elimination half life is about 35-50 hours and is consistent with once daily dosing. Amlodipine is extensively metabolised by the liver to inactive metabolites with 10% of the parent compound and 60% of metabolites excreted in the urine.

**Use in the elderly:** The time to reach peak plasma concentrations of amlodipine is similar in elderly and younger subjects. Amlodipine clearance tends to be decreased with resulting increases in AUC and elimination half-life in elderly patients. Increases in AUC and elimination half-life in patients with congestive heart failure were as expected for the patient age group studied.

### Composition

**Amocal® 5 mg Tablet:** Amlodipine Besilate BP 6.931 mg equivalent to Amlodipine 5 mg.

**Amocal® 10 mg tablet:** Amlodipine Besilate BP 13.862 mg equivalent to Amlodipine 10 mg.

**Indications:** Hypertension, Prophylaxis of chronic stable angina pectoris, Prinzmetal's (variant) angina when diagnosed by a cardiologist. In hypertensive patients, **Amocal®** is used in combination with a thiazide diuretic, alpha blocker, beta-adrenoceptor blocking agent, or an angiotensin converting enzyme inhibitor. For angina, **Amocal®** 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 blockers. **Amocal®** is well tolerated in patients with heart failure and a history of hypertension or ischaemic heart disease.

**Dosage and administration:** Usual dose is 5 mg once daily. The maximum dose is 10 mg once daily. Elderly patients with hepatic insufficiency may be started with a dose of 2.5 mg once daily. In hypertension, it may be used alone or in combination with other antihypertensive agents. For angina pectoris, 5-10 mg once daily is recommended.

**Contraindications:** Amlodipine is contra-indicated in patients with a known sensitivity to dihydropyridines, Amlodipine or any of the excipients. It should not be used in cardiogenic shock, clinically significant aortic stenosis, unstable angina (excluding Prinzmetal's angina).

**Side effects:** Dizziness, flushing, palpitation, hypotension, peripheral oedema, GI disturbance, increased frequency of micturition etc.

**Use in pregnancy and lactation:** **Amocal®** should not be prescribed in women known to be pregnant. It is probably best for mother to avoid the drug during lactation.

**Precautions:** It should be used with caution in patients with poor cardiac reserve, severe aortic stenosis and hepatic impairment.

**Drug Interactions:** Amlodipine has been safely administered with thiazide diuretics, alpha blockers, beta blockers, angiotensin-converting enzyme inhibitors, long-acting nitrates, sublingual glyceryl trinitrate, non-steroidal anti-inflammatory drugs, antibiotics, and oral hypoglycaemic drugs. In vitro data from studies with human plasma, indicate that amlodipine has no effect on protein binding of digoxin, phenytoin, warfarin or indomethacin.

**Overdosage:** Available data suggest that gross overdosage could result in excessive peripheral vasodilatation and possibly reflex tachycardia. Marked and probably prolonged systemic hypotension up to and including shock with fatal outcome have been reported. Administration of activated charcoal to healthy volunteers immediately or up to two hours after ingestion of amlodipine 10 mg has been shown to significantly decrease amlodipine absorption. Gastric lavage may be worthwhile in some cases. Clinically significant hypotension due to Amlodipine overdosage calls for active cardiovascular support including frequent monitoring of cardiac and respiratory function, elevation of extremities, and attention to circulating fluid volume and urine output. A vasoconstrictor may be helpful in restoring vascular tone and blood pressure, provided that there is no contraindication to its use. Intravenous calcium gluconate may be beneficial in reversing the effects of calcium channel blockade. Since Amlodipine is highly protein-bound, dialysis is not likely to be of benefit.

**Storage:** Store below 25°C, protected from light. Keep out of reach of children.

### Packaging

**Amocal® 5 mg Tablet:** Each carton contains 14X3 tablets in blister pack.

**Amocal® 10 mg Tablet:** Each carton contains 10X3 tablets in blister pack.



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