Amlodipine Besylate Tablets USP
AMLIN-5 / 10

POM

COMPOSITION :

Amlin - 5
Each uncoated tablet contains :
Amlodipine Besylate USP
Eq. to Amlodipine 5 mg
Excipients Q.S.

Amlin - 10
Each uncoated tablet contains :
Amlodipine Besylate USP
Eq. to Amlodipine 10 mg
Excipients Q.S.
Colour : Quinoline Yellow Lake

THERAPEUTIC CLASS :
Calcium Channel Blocker

PHARMACOLOGICAL ACTIONS :
Inhibits calcium ion from entering the "slow channels" or select voltage-sensitive areas of vascular smooth muscle and myocardium during depolarization, producing a relaxation of coronary vascular smooth muscle and coronary vasodilation; increases myocardial oxygen delivery in patients with vasospastic angina

Pharmacokinetics:
After oral administration of therapeutic doses of amlodipine, absorption produces peak plasma concentrations between 6 and 12 hours. Absolute bioavailability has been estimated to be between 64 and 90%. The bioavailability of amlodipine is not altered by the presence of food. Amlodipine is extensively (about 90%) converted to inactive metabolites via hepatic metabolism with 10% of the parent compound and 60% of the metabolites excreted in the urine. Elimination from the plasma is biphasic with a terminal elimination half-life of about 30-50 hours. Steady-state plasma levels of amlodipine are reached after 7 to 8 days of consecutive daily dosing.
The pharmacokinetics of amlodipine are not significantly influenced by renal impairment. Patients with renal failure may therefore receive the usual initial dose.
Elderly patients and patients with hepatic insufficiency have decreased clearance of amlodipine with a resulting increase in AUC of approximately 40-60%, and a lower initial dose may be required. A similar increase in AUC was observed in patients with moderate to severe heart failure.
Paediatric Patients : Sixty-two hypertensive patients aged 6 to 17 years received doses of amlodipine between 1.25 mg and 20 mg. Weight-adjusted clearance and volume of distribution were similar to values in adults.

INDICATIONS :
Amlodipine Besylate Tablets USP is indicated for hypertension, chronic stable angina and vasospastic angina (Prinzmetal's or variant angina). Amlodipine Besylate Tablets USP may be used as monotherapy or in combination with other antihypertensive or antianginal drugs.

CONTRAINDICATIONS :
Hypersensitivity to amlodipine or any component of the formulation

SPECIAL PRECAUTIONS & WARNINGS :
Increased angina and/or MI has occurred with initiation or dosage titration of calcium channel blockers. Use caution in severe aortic stenosis. Use caution in patients with severe hepatic impairment. Dosage titration should occur after 7-14 days on a given dose.
Pregnancy Implications :
Embryotoxic effects have been demonstrated in small animals. No well-controlled studies have been conducted in pregnant women. Use in pregnancy only when clearly needed and when the benefits outweigh the potential hazard to the foetus.
Lactation :
Excretion in breast milk unknown/not recommended

ADVERSE EFFECTS :
Amlodipine is well tolerated. Side effects include headache, oedema, fatigue, somnolence, nausea, abdominal pain, flushing, palpitations and dizziness.
Less commonly observed are pruritus, rash, dyspnoea, asthenia, muscle cramps and dyspepsia. Rarely, myocardial infarction and chest pain have been reported.

DOSAGE & ADMINISTRATION :
Hypertension :
Initial dose of 5 mg once daily, with a maximum dose of 10 mg once daily.
Small, fragile or elderly individuals or patients with hepatic insufficiency may be started on 2.5 mg once daily and this dose may be used when adding amlodipine to other anti-hypertensive therapy.
Chronic stable or vasospastic angina :
5-10 mg with a lower dose (2.5 mg) in the elderly and in patients with hepatic insufficiency.
Children :
The effective antihypertensive oral dose in paediatric patients (6-17 years) is 2.5 mg to 5 mg once daily. Doses in excess of 5 mg daily have not been studied in paediatric patients.

OVERDOSAGE :
Primary cardiac symptoms of calcium channel blocker overdose include hypotension and bradycardia. Noncardiac symptoms include confusion, stupor, nausea, vomiting, metabolic acidosis, and hyperglycemia. Treat other signs and symptoms symptomatically.

DRUG INTERACTIONS :
In clinical trials, amlodipine has been safely administered with thiazide diuretics, beta-blockers, angiotensin converting enzyme inhibitors, long acting nitrates, sublingual nitroglycerin, digoxin, warfarin, non-steroidal anti-inflammatory drugs, antibiotics and oral hypoglycemic drugs.

PRESENTATION :
Blister Pack / Jar Pack

STORAGE CONDITION :
Store below 30°C. Protect from light.

SHELF LIFE:
36 months

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Manufactured by :
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