AMLODIPINE

LODI

5 mg Tablet
10 mg Tablet

ANTIHYPERTENSIVE
(CALCIUM CHANNEL BLOCKER)

FORMULATION:
Each tablet contains:
Amlodipine (as besilate)..... 5mg, 10mg

PRODUCT DESCRIPTION:
Amlodipine 5 mg Tablet is a white to off-white, oval (ellipse), uncoated tablet, bisected on one side and plain on the other side. Amlodipine 10 mg Tablet is a white to off-white, oval, biconvex, uncoated tablet, plain on both sides.

PHARMACODYNAMICS AND PHARMACOKINETICS:
Amlodipine is a dihydropyridine calcium antagonist (calcium ion antagonist or slow-channel blocker) that inhibits the transmembrane influx of calcium ions into vascular smooth muscle and cardiac muscle. The contraction of the cardiac and vascular smooth muscle are dependent upon the movement of extracellular calcium ions into these cells through specific ion channels. Amlodipine inhibits calcium ion influx across cell membranes selectively, with a greater effect on vascular smooth muscle cells than on cardiac muscle cells. Amlodipine also exerts vasodilation to the peripheral arteries by direct action on the vascular smooth muscle causing a reduction in peripheral vascular resistance and blood pressure.

Amlodipine is well absorbed following oral administration with peak blood concentrations occurring after 6 to 12 hours. The bioavailability is about 60% - 65%. Amlodipine is reported to be about 97.5% bound to plasma proteins. It has a prolonged terminal elimination half-life of 35 to 50 hours and steady state plasma concentrations are not achieved until after 7 to 8 days of administration. Amlodipine is extensively metabolized in the liver; metabolites are mostly excreted in the urine together with less than 10% of a dose as unchanged drug.

INDICATIONS:
Amlodipine is used in the management of hypertension and angina pectoris. It may be used in combination with other antihypertensive and anti-anginal agents.

DOSAGE AND ADMINISTRATION:
The usual initial antihypertensive dose of Amlodipine is 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 antihypertensive therapy or as prescribed by a physician. Dose may be increased depending on the patient's response.
The recommended dose for chronic stable or vasospastic angina is 5-10 mg, with the lower dose suggested in the elderly and in patients with hepatic insufficiency. Most patients will require 10 mg for adequate effects or as prescribed by a physician.
Amlodipine is given by mouth as the besilate, but doses are usually expressed in terms of the base.

PRECAUTIONS:
Amlodipine should be used with caution in patients with hypotension, in patients whose cardiac reserve is poor and in those with heart failure since deterioration of heart failure has been noted. Amlodipine should not be used in cardiogenic shock, in patients who have recently suffered a myocardial infarction or in acute unstable angina. Amlodipine should not be used to treat an anginal attack in chronic stable angina. In patients with severe aortic stenosis, Amlodipine may increase the risk of developing heart failure. The dose may need to be reduced in patients with hepatic impairment. Amlodipine should be discontinued in patients who experience ischaemic pain following its administration and should be avoided in pregnancy.

CONTRAINDICATIONS:
Amlodipine is contraindicated in patients with known sensitivity to amlodipine. It is also contraindicated in patients suffering from cardiogenic shock, unstable angina, significant aortic stenosis and obesity.

PREGNANCY AND LACTATION:
Administration of drugs during pregnancy should only be considered if the expected benefit to the mother is greater than any possible risk to the fetus.
Amlodipine is excreted into human milk. Use is not recommended and a decision should be made to discontinue amlodipine or discontinue breastfeeding, taking into account the importance of the drug to the mother.

INTERACTIONS:
Amlodipine may enhance the antihypertensive effects of other antihypertensive drug such as beta blockers, although the combination is generally tolerated. It may modify insulin and glucose response and therefore, diabetic patients may need to adjust their antidiabetic treatment.

ADVERSE DRUG REACTIONS:
Abdominal pain, nausea, palpitations, flushing, oedema, headache, dizziness, sleep disturbances, fatigue, gastrointestinal disturbances, dry mouth, taste disturbances, hypotension, syncope, chest pain, dyspnea, mood changes, tremor, paresthesia, urinary disturbances, impotence, gynecomastia, weight change, myalgia, visual disturbances, pruritus, rashes (including erythema multiforme), alopecia, purpura, pancreatitis, hepatitis, jaundice, cholestasis, gingival hyperplasia, myocardial infarction, arrhythmia, vasculitis, hyperglycaemia, thrombocytopenia, angioedema and urticaria.

OVERDOSE AND TREATMENT:
Activated charcoal may be administered in case of overdosage. Hypotension may respond to placing the patients in supine position with the feet raised and the administration of plasma expanders. If hypotension is not corrected, calcium gluconate or calcium chloride should be given intravenously. If hypotension persists, intravenous administration of a sympathomimetic agent such as isoprenaline, dopamine or noradrenaline (norepinephrine) may be given. Dialysis is not useful as amlodipine is highly protein bound.

CAUTION:
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

For suspected adverse drug reaction, report to the FDA: **www.fda.gov.ph**
Patient should seek medical attention immediately at the first sign of any adverse drug reaction.

AVAILABILITY:
DRP-1357-06 - 5mg Tablet: Blister pack x 10's (Box of 30's)
DRP-1334-07 - 10mg Tablet: Blister pack x 10's (Box of 30's)

KEEP OUT OF REACH OF CHILDREN.

STORE AT TEMPERATURES NOT EXCEEDING 30°C.

DATE OF FIRST AUTHORIZATION:
5 mg Tablet: 04 August 2011
10 mg Tablet: 02 August 2011

DATE OF REVISION:
September 2021

Manufactured by:
HIZON LABORATORIES, INC.
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