xxxxxxxxx-5343

AMLODIPINE BESILATE

AMLOCOR 5 mg Tablet **Antihypertensive**

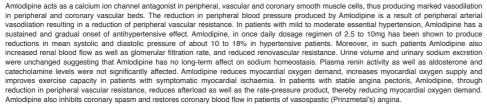
FORMULATION

Each tablet contains

Amlodipine Besilate equivalent to

Amlodipine

CLINICAL PHARMACOLOGY



Amlodipine has no significant effects on the sinoatrial or atrioventricular node. In clinical studies where Amlodipine was administered concomitantly with beta-blockers to patients with either hypertension or angina, no adverse effects on electrocardiographic parameters were observed.

Animal studies have demonstrated a cardioprotective effect for Amlodipine in both in-vivo and in-vitro models of ischaemic reperfusion; reductions in tissue calcium content and increase in shortening fraction have been noted after reperfusion. After oral administration of therapeutic doses, Amlodipine is slowly and almost completely absorbed; peak plasma concentration is attained within 6 to 12 hours with absolute bioavailability between 64 and 90%. The bioavailability of Amlodipine is not altered by the presence of food. Amlodipine has relatively long elimination half-life of 35 to 45 hours, which permits once-daily oral doses, to inactive metabolites with most metabolites excreted in the urine. Amlodipine is more that 95% bound to plasma proteins.

Amlodipine has been safely administered with thiazide diuretics, beta-adrenoceptor blocking drugs, angiotensin-converting enzyme inhibitors, long-acting nitrate, sublingual glyceryl trinitrate, non-steroidal anti-inflammatory drugs, antibiotics, and oral hypoglycaemic agents

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 pharmacokinetics of Amlodipine.

In healthy volunteers, co-administration of Amodipine did not significantly alter the effect of warfarin on prothrombin time. The introduction of Amlodipine is not likely to result in the need for modification of an established warfarin agents

INDICATION

Amlodipine is indicated as monotherapy for the first treatment of mild to moderate hypertension. It can also be used in combination with thiazide diuretics, beta adrenoceptor-blocker or angiotensin converting enzyme inhibitors of the patients not responding adequately to monotherapy with any of these antihypertensive agents.

For prophylaxis of angina

DOSAGE AND ADMINISTRATION

Adults: For both hypertension and angina, the recommended initial dose is 5mg. Amlodipine orally once daily which may be increased to a maximum dose of 10mg depending on the individual patient's response. Small, fragile or elderly patients & patients with hepatic insufficiency may be started on Amlodipine 2.5mg once daily and this dose may be used when adding Amlodipine to other antihypertensive or antianginal therapy. Amlodipine can be administered with or without food.

Use in elderly: Although elderly patients may have higher plasma concentrations of Amlodipine than younger patients the terminal elimination half-lives in both are similar. Amlodipine is similarly well-tolerated in elderly or younger patients. Therefore, the normal dosage of Amlodipine is recommended for elderly people.

Use in patients with renal impairment: Amlodipine is extensively metabolised to inactive metabolites with 10% of excreted drug in the urine. Changes in amlodipine plasma concentrations are not correlated with the degree of renal impairment; therefore, the normal dosage is recommended in patients with renal impairment. Amiodipine is not dialysable.

Use in patients with impaired hepatic function: The half-life of Amiodipine is prolonged in patients with impaired liver function. Amiodipine should

therefore be administered with caution in such patients.

CONTRAINDICATIONS

Amlodipine is contraindicated in patients with a known hypersensitivity to dihydropyridines (e.g. nifedipine, nicardipine, isradipine).

USE IN PREGNANCY, LACTATION AND CHILDREN

There is no clinical experience with Amlodipine in pregnancy or lactation. Amlodipine should not be administered during pregnancy or lactation or to women of child-bearing potential unless effective contraception is ensured. Since there is no clinical experience, use of Amlodipine is not currently recommended for children and adolescents of less than 18 years of age.

ADVERSE REACTIONS

Amlodipine is generally well tolerated. The most commonly observed side effects are headache, oedema, fatique, flushing and dizziness. Less common side effects include nausea, abdominal pain, somnolence and palpitations. Rare side effects include muscle cramps, frequency of micturition or nocturia, coughing, breathlessness, epistaxis, impotence, nervousness and conjunctivitis. No clinically significant pattern of laboratory test abnormalities related to Amlodipine has been observed.

Amlodipine has not been associated with any adverse effects or changes in plasma lipids. Amlodipine has been used safely in patients with well

compensated congestive heart failure, peripheral vascular disease, chronic obstructive pulmonary disease, abnormal lipid profiles and diabetes

WARNING/PRECAUTION

The half-life of amlodipine is prolonged in patients with impaired liver function; Amlodipine should be administered with caution in patients receiving either peripheral vasaodilators (especially in patients with severe aortic stenosis) or in patients with severe heart failure

OVERDOSAGE

There is no well documented experience with Amlodipine overdosage. Since absorption of Amlodipine is slow, gastric lavage should be performed. Available data suggests that the gross overdosage could result in excessive peripheral vasodilation with subsequent marked and probably prolonged hypotension, which calls for active cardiovascular support including monitoring of cardiac and respiratory function, elevation of extremeties, attention to circulating fluid volume and urine output. Intravenous calcium gluconate may help to reverse the effects of calcium entry blockade. A vasoconstrictor agent may be helpful in restoring vascular tone and blood pressure provided there is no contraindication to its use. Since Amlodipine is highly protein bound, dialysis is unlikely to be of benefit.

STORAGE CONDITION

Store at temperatures not exceeding 25°C. Protected from light and moisture.

CAUTIONFoods, Drugs, Devices & Cosmetics Act prohibits dispensing without prescription

Amlodipine Besilate (Amlocor) 5 mg Tablet - PVC/Alu Blister, 10 Tablets per strip : Box of 30's



Manufactured by : TORRENT PHARMACEUTICALS LTD. Indrad-382 721, Dist. Mehsana, INDIA.

Imported and Distributed by : TORRENT PHARMA PHILIPPINES INC. Unit 601, 6/F, ITC Building, 337 Sen. Gil Puyat Avenue, Makati City, PHILIPPINES