LIPIROL-AM

Each tablet contains:

Composition:

Atorvastatin…….....10 mg

Amlodipine…….... 5 mg

Indications:

Lipirol-Am is a prescription drug. It is used in patients with multiple risk factors for heart disease such as family history, high blood pressure, age, low HDL or smoking to reduce the risk of heart attack and stroke.

CONTRA-INDICATIONS

Amlodipine is contraindicated in patients with a known sensitivity to dihydropyridines, amlodipine, or any of the inert ingredients.

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WARNINGS

Use in the Elderly

Elderly patients may have higher plasma concentrations of amlodipine than those in the younger patients. The time to reach peak plasma concentrations of amlodipine is similar in elderly and younger subjects. Amlodipine clearance is decreased with resulting increases in AUC (approximately 40-60%) and elimination half-life in elderly and hepatically insufficient patients. A similar increase in AUC was observed in patients with moderate to severe heart failure. Elderly patients should start on a lower dose.

Amlodipine is extensively metabolised to inactive metabolites with 10% excreted unchanged in the urine. Changes in amlodipine plasma concentrations are not correlated with mild renal impairment. NORVASC may be used in such patients at normal doses. In patients with severe renal impairment, amlodipine dosages may need to be reduced. Amlodipine is not dialysable.

Amlodipine half-life is prolonged in patients with impaired liver function. Amlodipine should therefore be administered at lower (5 mg) initial dose in these patients.

Use in Children

Safety and effectiveness of amlodipine in children has not been established.

COMPATIBILITY WITH OTHER MEDICINES

Amlodipine may be administered with thiazide diuretics, beta blockers, angiotensin-converting enzyme inhibitors, long-acting nitrates, sublingual nitroglycerine, non-steroidal antiinflammatory drugs, antibiotics, and oral hypoglycemic medicines.

Studies have indicated that the co-administration of NORVASC with digoxin did not change serum digoxin levels or digoxin renal clearance in normal volunteers, and that coadministration of cimetidine did not alter the pharmacokinetics of NORVASC.

In vitro data from studies with human plasma indicate that amlodipine has no effect on protein binding of the medicines tested (digoxin, phenytoin, warfarin, or indomethacin).In healthy male volunteers, the co-administration of amlodipine does not significantly alter the effect of warfarin on prothrombin response time.

SIDE EFFECTS AND SPECIAL PRECAUTIONS

The most commonly observed side effects were headache, oedema, fatigue, somnolence, nausea, flushing, palpitations and dizziness. Vomiting and abdominal pain have occurred.
Less commonly observed side effects include alopecia, altered bowel habits, arthralgia, asthenia, back pain, dyspepsia, dyspnea, gingival hyperplasia, gynecomastia, hyperglycemia impotence, increased urinary frequency, leucopenia, malaise, mood changes and depression, dry mouth muscle cramps, myalgia, peripheral neurophathy, pancreatitis, increased sweating, syncope, thrombocytopenia, vasculitis, and visual disturbances
Allergic reactions including pruritus, rash, angioedema and erythema multiforme have also been observed.
The following adverse events have been reported but cannot be distinguished from the natural history of the underlying disease: myocardial infarction, arrhythmia (including ventricular tachycardia and atrial fibrillation) and chest pain.

Hepatitis and jaundice and hepatic enzyme elevations have been reported (mostly consistent with cholestasis). Some cases severe enough to require hospitalisation have been reported in association with use of amlodipine.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

There is no well documented experience with amlodipine overdosage. Gastric lavage may be worthwhile. Available data suggest that gross overdosage could result in excessive peripheral vasodilation with subsequent marked and probably prolonged systemic hypotension. Clinically significant hypotension due to amlodipine overdosage calls for active cardiovascular support. 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.

Dosage : As per the physician's advice.
Presentations: 15 tablets

MRP	Retailer	Stockist
28.90	23.12	20.80