1.6.3 Patient information leaflet (PIL)

MYLOVASC®-2.5/5 Tablets

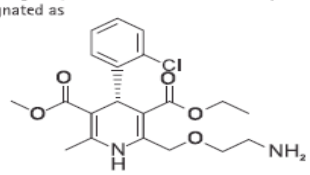
(S - AMLODIPINE BESILATE TABLETS 2.5 / 5 MG)

COMPOSITION:

MYLOVASC – 2.5 TABLETS:
Each uncoated tablet contains: S-Amlodipine Besilate equivalent to S-Amlodipine 2.5 mg

MYLOVASC- 5 TABLETS:
Each uncoated tablet contains: S-Amlodipine Besilate equivalent to S-Amlodipine 5.0 mg

DESCRIPTION:
S(-) Amlodipine is the pharmacologically active isomer of Amlodipine. S(-) Amlodipine is chemically designated as S(-) 3-ethyl-5-methyl-2-(2-aminoethoxymethyl)-4-(2-chlorophenyl)-1,4-dihydro-6-methyl-3,5-pyridinedicarboxylate benzenesulphonate. Its empirical formula is $CHClN.O.C.H.O.S$ with the molecular weight of 567.1



MECHANISM OF ACTION:
S(-) Amlodipine is the active enantiomer of amlodipine. It blocks the passage of calcium ions into the vascular smooth muscle cells and myocardial cells during depolarisation resulting in relaxation of coronary vascular smooth muscle and coronary vasodilatation. It also helps to increase the delivery of oxygen to the myocardial tissues in patients with vasospastic angina.

PHARMACODYNAMICS:
S(-) Amlodipine, the chirally pure form of Amlodipine, is a calcium channel antagonist belonging to the dihydropyridine class. The S(-) isomer of Amlodipine is found to possess greater pharmacological effects than R(+) Amlodipine. S(-) Amlodipine is 1000 times more potent than the R(+) isomer in binding to the dihydropyridine receptor. In humans, the dominant effects of Amlodipine are consuquent to vasodilation. S(-) Amlodipine lowers peripheral vascular resistance without causing a reflex tachycardia. It is effective as a once daily dosage in the control of hypertension.

PHARMACOKINETICS AND METABOLISM:
Administration of S(-) Amlodipine 2.5mg as a single dose in the fasting state produced maximum plasma concentration (C_{max}) of 8.30 ± 1.071 ng/ml in 2.73 ± 0.88 hrs. (T_{max}). 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 urine. Ex vivo studies have shown that approximately 93% of the circulating drug is bound to plasma proteins in hypertensive patients. The mean AUC 0-t value (t=48 hrs) of tablets S(-) Amlodipine (2.5mg) is 95.33 ± 14.45ng.hr/ml. The AUC 0-∞ value is recorded to be 140.91 ± 28.06ng.hr/ml. The plasma elimination half life of S(-) Amlodipine has been found to be 31.09 ± 12.65hrs.

INDICATIONS:
Hypertension: Mylovasc (S-Amlodipine Besilate) tablet is indicated for the treatment of hypertension. It may be used alone or in combination with other antihypertensive agents.

DOSAGE:
The normal recommended dose is 2.5mg once a day for the treatment of hypertension. Based on the clinical response of the patient, the dose may be enhanced, upto 5mg once a day.

Manufactured for:
Prisma Pharma FZE
P. O. Box 17269
Jebel Ali Free Zone
Dubai, U.A.E.

PRISMA®
A RAY OF HOPE

ADMINISTRATION:
Take this medication by mouth, usually once daily with or without food or as directed by your doctor.

CONTRAINDICATION:
Mylovasc is contraindicated in patients with liver insufficiency and pregnancy. Hypersensitivity to any of the component of the formulation.

ADVERSE EFFECTS:
On the basis of clinical data available, the following adverse events have been reported in less than 2% of patients: vertigo (0.05%), tachycardia (0.05%), cough (0.05%), headache (0.43%), difficulty in breathing (0.1%), edema (0.75- 1.92%), cheerlessness (0.05%) and facial puffiness (0.05%). These side effects were mild in nature.

PRECAUTION:
No controlled clinical study of S(-) Amlodipine has been performed in patients with hepatic impairment and renal impairment. Clinical studies in patients with normal liver function have shown that there is no elevation in the hepatic enzymes with the use of S(-) Amlodipine. However, caution should be taken while administering S(-) Amlodipine to patients with hepatic and renal impairments.

PREGNANT WOMEN AND NURSING MOTHER:
There is no data available on the use of S(-) Amlodipine in pregnant and lactating women, hence the drug should be administered only when the potential benefits outweighs the risk to the patients.

CHILDREN:
Safety and effectiveness of this product in children has not been established.

DRUG INTERACTIONS:
Clinical studies have shown that S(-) Amlodipine when combined with aspirin, nitrates, beta-blockers, statins, ACE inhibitors, H2 blockers and proton pump inhibitors produced no drug interactions.

OVERDOSAGE:
There are no reported case of overdosage with the use of S(-) Amlodipine. Overdosage with racemic Amlodipine may cause excessive peripheral vasodilation with marked hypotension and possible a reflex tachycardia. Hence caution should be taken in case of an overdosage with S(-) Amlodipine. If massive overdose occurs, active cardiac and respiratory monitoring should be instituted. Frequent blood pressure measurements should be performed. If hypotension occurs, cardiovascular support including elevation of the extremities and the iudious administration of fluids be initiated. If hypotension remains unresponsive to these conservative measures, administration of vasopressors (such as phenylephrine) should be considered with attention to the circulating drug. If massive overdose occurs, gastric lavage should be employed. As this product is highly plasma protein bound, haemodialysis is not likely be of benefit.

STORAGE:
Store in the original package below 30°C. Keep out of the reach of children. Store away from heat and direct light.

MEDICINE CLASSIFICATION:
Prescription Medicine

PRESENTATIONS:
Blister Packing: 3 x 10 Tablets.

Mfg. Lic. No:
TN/DRUGS/TN00002269

Manufactured by:
Bafna Pharmaceuticals Ltd.
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Grantlyon Village
Chennai – 600052, India

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