

Lovapres 5

Amlodipine

COMPOSITION

Each tablet contains Amlodipine Besilate BP equivalent to Amlodipine 5 mg.

PHARMACOLOGY

Lovapres 5 (Amlodipine) is a long-acting calcium channel blocker that inhibits the transmembrane influx of calcium ions into vascular smooth muscle and cardiac muscle. Thus it causes reduction in peripheral vascular resistance and contractile process in cardiac muscle and reduces blood pressure.

INDICATIONS

Lovapres 5 (Amlodipine) is a calcium channel blocker and may be used alone or in combination with other antihypertensive and antianginal agents for the treatment of Hypertension and Coronary Artery Disease (such as Chronic Stable Angina, Vasospastic Angina and Angiographically Documented Coronary Artery Disease in patients without heart failure or an ejection fraction < 40%) .

DOSAGE AND ADMINISTRATION

Adult: Starting dose 5 mg once daily with maximum dose 10 mg once daily.

Small, Fragile and Elderly patients or patients with hepatic insufficiency: Starting dose 2.5 mg once daily.

Paediatric: Starting dose 2.5 mg to 5 mg once daily.

CONTRAINDICATIONS

It is contraindicated in patients with known sensitivity to Amlodipine.

WARNING AND PRECAUTION

Symptomatic hypotension is possible, particularly in patients with severe aortic stenosis. However, because of the gradual onset of action, acute hypotension is unlikely. Worsening angina and acute myocardial infarction can develop after starting or increasing the dose of Amlodipine, particularly in patients with severe obstructive coronary artery disease. Titrate slowly when administering calcium channel blockers to patients with severe hepatic impairment.

SIDE EFFECTS

Most common side effects are headache and edema which occurred in a dose related manner. Other side effects not dose related but reported with an incidence >1.0% are headache, fatigue, nausea, abdominal pain and somnolence.

USE IN PREGNANCY AND LACTATION

Pregnancy Category C. There are no adequate and well-controlled studies of Amlodipine in pregnant women. Amlodipine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. It is not known whether Amlodipine is excreted in human milk. In the absence of this information, it is recommended that nursing be discontinued while Amlodipine is administered.

USE IN CHILDREN AND ADOLESCENTS

Amlodipine is not recommended for use in children less than 6 years of age.

DRUG INTERACTIONS

Amlodipine has been safely administered with thiazide diuretics, alpha blockers, beta blockers, angiotensin-converting enzyme inhibitors, long-acting nitrates, sublingual nitroglycerine, non-steroidal anti-inflammatory drugs, antibiotics and oral hypoglycemic drugs. Amlodipine has no effect on protein binding of Digoxin, Phenytoin, Warfarin or Indomethacin. Administration of Amlodipine with grapefruit or grapefruit juice is not recommended as bioavailability may be increased in some patients resulting in increased blood pressure lowering effects.

OVERDOSAGE

Overdosage might be expected to cause excessive peripheral vasodilation with marked hypotension and possibly a reflex tachycardia. Hemodialysis is not likely to be of benefit.

STORAGE

Store below 30°C temperature in a cool and dry place. Protect from light and moisture. Keep out of the reach of children.

HOW SUPPLIED

Each box contains 50 tablets in Alu-PVC blister pack.