

## Lamocard- 5 Tablet

Levamlodipine INN 5mg

**Presentation:** Each tablet contains Levamlodipine 5.00 mg as Levamlodipine Maleate INN 6.40mg.

**Pharmacology:** 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. Experimental data suggest that amlodipine binds to both dihydropyridine and nondihydropyridine binding sites. The contractile processes of cardiac muscle 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.

**Indication:** S-Amlodipine is calcium channel blocker and may be used alone or in combination with other antihypertensive agents for the treatment of hypertension, to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions.

**Dosage & Administration: Adults:** The usual initial antihypertensive oral dose of S-Amlodipine is 2.5 mg once daily, and the maximum dose is 5 mg once daily. Small, fragile, or elderly patients, or patients with hepatic insufficiency may be started on 1.25 mg once daily and this dose may be used when adding S-Amlodipine to other antihypertensive therapy. Adjust dosage according to blood pressure goals. In general, wait 7 to 14 days between titration steps. **Children:** The effective antihypertensive oral dose in pediatric patients ages 6-17 years is 1.25 mg to 2.5 mg once daily. Doses in excess of 2.5 mg daily have not been studied in pediatric patients. Or, as directed by the registered physician.

**Contraindications:** S-Amlodipine is contraindicated in patients with known sensitivity to amlodipine.

**Precautions: Hypotension:** Symptomatic hypotension is possible, particularly in patients with severe aortic stenosis. Because of the gradual onset of action, acute hypotension is unlikely. Increased Angina or Myocardial Infarction: 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. Patients with Hepatic Failure: Because amlodipine is extensively metabolized by the liver and the plasma elimination half-life ( $t_{1/2}$ ) is 56 hours in patients with impaired hepatic function, titrate slowly when administering amlodipine to patients with severe hepatic impairment.

**Side Effects:** Most common adverse reactions to amlodipine is edema which occurred in a dose related manner. Other adverse experiences not dose related but reported with an incidence >1.0% are fatigue, nausea, abdominal pain and somnolence.

**Use in Pregnancy & Lactation:** The limited available data based on post-marketing reports with amlodipine use in pregnant women are not sufficient to inform a drug-associated risk for major birth defects and miscarriage. There are risks to the mother and fetus associated with poorly controlled hypertension in pregnancy.

**Use in child:** S-Amlodipine (1.25 to 2.5 mg daily) is effective in lowering blood pressure in patients 6 to 17 years. The effect of S-Amlodipine on blood pressure in patients less than 6 years of age is not known.

**Drug Interaction: Impact of Other Drugs on Amlodipine-CYP3A Inhibitors:** Co-administration with CYP3A inhibitors (moderate and strong) results in increased systemic exposure to amlodipine and may require dose reduction. Monitor for symptoms of hypotension and edema when amlodipine is co-administered with CYP3A inhibitors to determine the need for dose adjustment. **CYP3A Inducers:** No information is available on the quantitative effects of CYP3A inducers on amlodipine. Blood pressure should be closely monitored when amlodipine is co-administered with CYP3A inducers, Sildenafil: Monitor for hypotension when sildenafil is co-administered with amlodipine. **Impact of Amlodipine on Other Drugs: Simvastatin:** Co-administration of simvastatin with amlodipine increases the systemic exposure of simvastatin. Limit the dose of simvastatin in patients on amlodipine to 20 mg daily.

**Overage:** No data available.

**Storage:** Store below 30°C in a dry place. Keep out of reach of children.

**Packing:** Each box contains 30's tablets in blister pack.



Manufactured by  
**DRUG INTERNATIONAL LTD.**  
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