

L-Amlo

Levamlodipine Maleate INN

Composition

L-Amlo 1.25 Tablet: Each tablet contains Levamlodipine Maleate INN equivalent to Levamlodipine 1.25 mg.

L-Amlo 2.5 Tablet: Each tablet contains Levamlodipine Maleate INN equivalent to Levamlodipine 2.5 mg.

L-Amlo 5 Tablet: Each tablet contains Levamlodipine Maleate INN equivalent to Levamlodipine 5 mg.

Pharmacology

Levamlodipine, also known as S-amlopidine, is a pharmacologically active enantiomer of amlodipine and an antihypertensive medication. Levamlodipine belongs to the dihydropyridine group of calcium channel blockers. It blocks the transmembrane influx of calcium through L-type calcium channels into the vascular and cardiac smooth muscles resulting in vasodilation and a decrease in blood pressure. It inhibits calcium influx in vascular smooth muscle to a greater degree than in cardiac muscle, leading to decreased peripheral vascular resistance and lowered blood pressure.

Indication

L-Amlo is a calcium channel blocker which is used alone or in combination with other antihypertensive agents for the treatment of hypertension. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions.

Dose & Administration

● Adult recommended dose: 2.5 mg orally once daily with maximum dose 5 mg once daily.

For small, fragile or elderly patients or patients with hepatic insufficiency, 1.25 mg once daily starting dose is recommended.

● Paediatric starting dose: 1.25 mg to 2.5 mg once daily or as directed by the physicians.

Contraindication

Levamlodipine is contraindicated in patients with known sensitivity to Amlodipine.

Warning & Precaution

● Symptomatic hypotension is possible, particularly in patients with severe aortic stenosis. However, 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.

● The dose should be titrated slowly in patients with severe hepatic impairment.

Side Effects

The most common side effects of Levamlodipine include swelling of legs or ankles, tiredness, nausea, stomach pain, sleepiness, dizziness, flushing (hot or warm feeling in face), heart palpitations (very fast heartbeat). Levamlodipine may cause serious side effects, including low blood pressure (hypotension).

Use In Pregnancy & Lactation

Pregnancy: The limited available data on amlodipine use in pregnant women are not sufficient to inform a drug-associated risk for major birth defects and miscarriage. Hypertension increases the fetal risk for intrauterine growth restriction and intrauterine death. Pregnant women with hypertension should be carefully monitored and managed accordingly by physician.

Lactation: No adverse effects of amlodipine on the breastfed infant have been observed. There is no available information on the effects of amlodipine on milk production.

Use In Children & Adolescents

L-Amlo (1.25 to 2.5 mg daily) is effective in lowering blood pressure in patients 6 to 17 years.

Effect of L-Amlo 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 results in increased systemic exposure to Amlodipine and may require dose reduction. Symptoms of hypotension and edema should also be monitored to determine the need for dose adjustment.

CYP3A Inducers: No information is available on the effects of CYP3A inducers on Amlodipine. Blood pressure should be closely monitored when Amlodipine is co-administered with CYP3A inducers.

Sildenafil: Hypotension should be monitored 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. Dose of Simvastatin in patients on Amlodipine should be limited to 20 mg daily.

Immunosuppressants: Amlodipine may increase the systemic exposure of Cyclosporine or Tacrolimus when co-administered. Frequent monitoring of trough blood levels of Cyclosporine and Tacrolimus is recommended and the dose should be adjusted when appropriate.

Overdose

Over dosage might be expected to cause excessive peripheral vasodilation with marked hypotension and possibly a reflex tachycardia. In humans, experience with intentional over dosage of amlodipine is limited. Active cardiac and respiratory monitoring should be initiated, if massive overdose occurs.

Storage

Store below 30°C. away from light and in a dry place. Keep out of the reach of children.

Packing

L-Amlo 1.25 Tablet: Each box contains 3 x 10 tablets in Alu-Alu blister pack & an insert.

L-Amlo 2.5 Tablet: Each box contains 3 x 10 tablets in Alu-Alu blister pack & an insert.

L-Amlo 5 Tablet: Each box contains 3 x 10 tablets in Alu-Alu blister pack & an insert.

Manufactured by:

Navana Pharmaceuticals Ltd.

Rupshi, Ruppaganj, Narayanganj, Bangladesh

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 **NAVANA PHARMA**
JAHURUL ISLAM COMPANY