

Amlevo™

Levamlodipine Besylate INN Tablet

DESCRIPTION

Amlevo™ is a preparation of Levamlodipine. Levamlodipine is a calcium antagonist (calcium channel blocker) of the dihydropyridine group and inhibits the transmembrane influx of calcium ions into cardiac and vascular smooth muscle. The mechanism of the antihypertensive action of Levamlodipine is due to a direct relaxant effect on vascular smooth muscle.

INDICATIONS

Amlevo™ 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 stroke and myocardial infarction.

Amlevo™ is also indicated for-

- Myocardial Ischaemia
- As monotherapy or in combination with other antianginal drugs in patients with angina

DOSAGE AND ADMINISTRATION

Adult: Starting dose 2.5 mg once daily with maximum dose 5 mg once daily.

CONTRAINDICATIONS

Levamlodipine is contraindicated in patients with a known sensitivity to dihydropyridines (e.g. Nifedipine, Nicardipine, Isradipine).

PRECAUTIONS AND WARNINGS

Use during pregnancy and lactation: Although some dihydropyridine compounds have been found to be teratogenic in animals, data in the rat and rabbit for Levamlodipine provide no evidence for a teratogenic effect.

There is, however no clinical experience with Levamlodipine in pregnancy or lactation.

To be dispensed only by the prescription of a registered physician.

DRUG INTERACTIONS

Levamlodipine has been safely administered with thiazide diuretics, beta-adrenoceptor blocking drugs, angiotensin-converting enzyme inhibitors, long-acting nitrates, sublingual glyceryl trinitrate, non-steroidal anti-inflammatory drugs, antibiotics and oral hypoglycaemic agents. Co-administration of Levamlodipine with digoxin did not change serum digoxin levels or digoxin renal clearance in normal volunteers. In healthy volunteers, co-administration of Levamlodipine did not significantly alter the effect of warfarin on prothrombin time. The introduction of Levamlodipine is not likely to result in the need for modification of an established warfarin regimen. In vitro data from studies with human plasma indicates that Levamlodipine has no effect on protein binding of digoxin, phenytoin, warfarin or indomethacin.

SIDE-EFFECTS

Levamlodipine is well tolerated. In placebo controlled clinical trials involving patients with hypertension or angina, the most commonly observed side-effects were-

- Headache • Fatigue • Nausea • Flushing and Dizziness • Chest Tightness.

No clinically significant pattern of laboratory test abnormalities related to Levamlodipine has been observed.

OVERDOSE

There is no well documented experience with Levamlodipine overdosage. Since Levamlodipine absorption is slow, gastric lavage may be worthwhile in some cases. Clinically significant hypotension due to Levamlodipine overdosage calls for active cardiovascular support including monitoring of cardiac and respiratory function, elevation of extremities and attention to circulating fluid volume and urine output. A vasoconstrictor agent may be helpful in restoring vascular tone and blood pressure, provided that there is no contraindication to its use. Since Levamlodipine is highly protein-bound, dialysis is unlikely to be of benefit.

STORAGE CONDITION

Store at or below 25° C temperature. Keep away from light and wet place. Keep out of reach of children.

PACKAGING

Amlevo™ 2.5 Tablet: Box containing 3 strips of 10 tablets each. Each tablet contains Levamlodipine Besylate INN equivalent to 2.5 mg Levamlodipine.

Amlevo™ 5 Tablet: Box containing 3 strips of 10 tablets each. Each tablet contains Levamlodipine Besylate INN equivalent to 5 mg Levamlodipine.

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Manufactured by

ESKAYEF PHARMACEUTICALS LTD.

TONGI, GAZIPUR, BANGLADESH

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