

Amlotab[®]

Amlodipine

Presentation

Amlotab[®] 5 tablet: Each tablet contains Amlodipine Besilate BP equivalent to Amlodipine 5 mg.

Description

Amlodipine is a Dihydropyridine Calcium antagonist that inhibits the transmembrane influx of Calcium ions into cardiac and vascular smooth muscle. It has greater affinity towards vascular smooth muscle than on cardiac muscle. Amlodipine is peripheral vasodilator that acts directly on vascular smooth muscle to cause a reduction in peripheral vascular resistance and thereby reduces blood pressure. Amlodipine reduces tone, decreases coronary vasoreactivity and lowers cardiac oxygen demand by reducing after load.

Indications

- Patients with mild to moderate hypertension (alone or in combination with other antihypertensives).
- The treatment of chronic stable and vasospastic angina.
- Raynaud's disease.

Dosage and Administration

For treatment of both hypertension and angina pectoris, the usual initial dose is 5 mg once daily. If the desired therapeutic effect cannot be achieved within 2-4 weeks, the dose may be increased to a maximum dose of 10 mg once daily. Amlodipine 10 mg once daily provide symptomatic improvement in patients with Raynaud's disease.

Side effects

Amlodipine is generally well tolerated. The most commonly observed side effects are headache, peripheral oedema, palpitations, flushing, dizziness, nausea, abdominal pain.

Contraindications

- Hypersensitivity to amlodipine or other calcium channel antagonist
- Severe hypertension

Precautions

Use in renal failure

Although amlodipine is excreted primarily via the kidney, mild renal impairment does not appear to have an effect on the plasma concentrations. Severe renal impairment may however require a dosage reduction. Amlodipine is not dialyzable.

Use in patients with impaired hepatic function

Amlodipine half-life is prolonged in patient with impaired hepatic function. Amlodipine should therefore be administered at lower (5mg) initial dose in these patients.

Use in heart failure

An increase number of pulmonary oedema has been reported.

Use in pregnancy and lactation

Pregnancy: Safety in pregnancy has not been established.

Lactation: It is not known whether amlodipine is excreted in breast milk. It is advised to stop breastfeeding during treatment with amlodipine.

Use in children

Use of amlodipine in children (under 12 years of age) is not recommended.

Drug interactions

Amlodipine may potentiate the effect of other antihypertensive (e.g. Beta-blocker, ACE-inhibitors, Alpha-1-blockers and Diuretics). In clinical interaction studies, Amlodipine did not affect the pharmacokinetics of Atorvastatin, Digoxin, Warfarin or Cyclosporine.

Overdosage

There is no well documented experience with amlodipine overdosage. In case of clinically significant hypotension due to amlodipine over dosage, calls for active cardiovascular support including monitoring of cardiac and respiratory function, elevation of extremities and attention to circulating fluid volume and urine output. Since Amlodipine is highly protein-bound, dialysis is unlikely to be of benefit.

Storage

Do not store above 30 °C. Keep away from light and out of the reach of children.

Commercial pack

Amlotab[®] 5 tablet: Each box contains 5 blister strips of 10 tablets.

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 **Incepto Pharmaceuticals Ltd**
Savar, Dhaka, Bangladesh
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