

Dopin 5

Amlodipine

COMPOSITION:

Dopin 5 Tablet: Each tablet contains Amlodipine Besilate BP equivalent to Amlodipine 5 mg.

PHARMACOLOGY:

Dopin 5 (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.

Dopin 5 is slowly and incompletely absorbed, with 60-80% of an oral dose reaching the systemic circulation. Plasma half life ranges from 30-60 hrs (mean 35.7 hrs). **Dopin 5** is extensively metabolized in the liver prior to excretion with only about 5% unchanged drug excreted in the urine.

INDICATION:

Patients with mild to moderate hypertension (alone or in combination with other antihypertensive). The treatment of chronic stable and vasospastic angina, Reynaud'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 provides symptomatic improvement in patients with Raynaud's disease.

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

CONTRAINDICATION:

Hypersensitivity to amlodipine or other calcium channel antagonist severe hypertension.

SIDE EFFECTS:

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

PRECAUTIONS:

Use in renal failure: Although Amlodipine is excreted primarily via 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 increased number of pulmonary oedema has been reported.

USE IN PREGNANCY AND LACTATION:

Pregnancy: No data are available at the present time. Therefore amlodipine should not be prescribed in women known to be pregnant.

Lactation: No data are available at the present time, so it is probably best for breast-feeding mothers to avoid the drug.

DRUG INTERACTIONS:

Digoxin: Absence of any interaction between amlodipine and digoxin in healthy volunteers has been documented in a controlled clinical study.

Warfarin: An unpublished study in healthy volunteers indicates that amlodipine does not significantly alter the effect of warfarin on prothrombin time.

Cimetidine: An unpublished clinical study indicated no interaction between amlodipine & cimetidine in healthy volunteers.

Food: Food does not alter the rate or extent of absorption of amlodipine.

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.

PHARMACEUTICAL PRECAUTION:

Dopin 5 (Amlodipine) tablet should be stored at a cool and dry place, protect from light and moisture.

HOW SUPPLIED:

Dopin 5 Tablet: Each box contains 3x10 tablets in Alu-Alu blister pack.

Manufactured by:



MEDICON Pharmaceuticals Ltd.
Mirpur, Dhaka, Bangladesh