

AMOLAB

(AMLODIPINE BESILATE 5 MG)

COMPOSITION:

Each tablet contains: Amlodipine 5mg as Amlodipine Besilate BP

PHARMACOLOGY:

Amlodipine is a dihydropyridine calcium channel blocker used in the management of hypertension and angina pectoris.

Administration of amlodipine results primarily in vasodilation with reduced peripheral resistance, blood pressure and after load increased coronary blood flow and a reflex increase in heart rate. This in turn results in an increase in myocardial oxygen supply and cardiac output.

PHARMACOKINETICS:

Amlodipine is well absorbed following oral administration with peak blood concentration occurring after 6 – 12 hours. The bioavailability is about 60-65%. Amlodipine is about 97.5% bound to plasma proteins. It has a prolonged terminal elimination half-life of 35 – 50 hours and steady state plasma concentrations are not achieved until after 7-8 days of administration.

Amlodipine is extensively metabolized in the liver; metabolites are mostly excreted in urine together with less than 10% of a dose as unchanged drug.

DOSAGE AND ADMINISTRATION:

Hypertension: The usual initial dose is 5mg once daily increased, if necessary, to 10mg once daily.

Angina (Stable and Prinzmetal's angina) similar doses.

ADVERSE EFFECTS:

The most common adverse effects of **Amolab** are associated with its vasodilator action and often diminish on continued therapy, they include: dizziness, flushing headache, hypotension, peripheral oedema, tachycardia, palpitation and fatigue.

TREATMENT OF ADVERSE EFFECTS

In recent overdosage (within 1 hour) with **Amolab** by mouth, the stomach may be emptied by lavage; activated charcoal may be administered. Supportive and symptomatic care should be given. Hypotension may respond to placing the patient in the supine position with the feet raised and the administration of plasma expanders, although cardiac overload should be avoided. If hypotension is not corrected, calcium gluconate or calcium chloride should be given IV. Glucagon may also be used. If hypotension persists, IV administration of a sympathomimetic such as isoprenaline, dopamine or noradrenaline may also be necessary. Dialysis is not useful as amlodipine is highly protein bound.

PRECAUTIONS

Amolab should be used with caution in patients with hypotension, in patients whose cardiac reserve is poor and in those with heart failure.

Amolab should not be used in cardiogenic shock, in patients who have recently suffered a myocardial infarction, or in acute unstable angina, or to treat an anginal attack in chronic stable angina.

Sudden withdrawal of **Amolab** may be associated with an exacerbation of angina.

The dose may need to be reduced in patients with impaired hepatic function.

Amolab should be discontinued in patients who experience ischaemic pain following its administration.

Amlodipine has been associated with acute attacks of porphyria and therefore **Amolab** is considered unsafe in porphyric patients. Amlodipine may modify insulin and glucose responses in patients with diabetes mellitus thus necessitating treatment modification.

INTERACTIONS

Amolab may enhance the antihypertensive effects of other antihypertensive drugs such as betablockers although the combination is well tolerated.

Antipsychotics: enhanced antihypertensive effects that may cause hypotension

Amlodipine is extensively metabolized in the liver by the cytochrome P. 450 enzyme system, and interactions may occur with other drugs sharing the same pathway (quinidine), enzymes inducers (carbamazepine, phenytoin, rifampicin), and enzyme inhibitors (cimetidine, erythromycin).

LEGAL CATEGORY: Prescription Only Medicine (P.O.M)

STORAGE CONDITIONS:- **Amolab** tablets should be stored in a dry place below 30°C. Protect from light. Keep all medicines out of reach of children.

SHELF-LIFE: As per the product label.

PRODUCT PRESENTATION AND AVAILABILITY: **Amolab** tablets is available in blister packs of 3 X 10's and 10 x 10's tablets.

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LICENCE HOLDER: LABORATORY & ALLIED LTD.



Laboratory & Allied Ltd.

Plot No. 209/10349, Mombasa Road,
P.O. Box 42875, Nairobi, Kenya

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