

# Vespin Tablets

(Amlodipine Besylate)

ویسپین ٹیبلٹس

(ایم لودیپین بیسیلیٹ)

## Description

Vespin (Amlodipine besylate) is a dihydropyridine derivative and has the following chemical name: 3-ethyl 5-methyl 2-(2-aminoethoxymethyl) 4-(2-chlorophenyl) 1,4-dihydro-6-methyl 3,5 pyridinedicarboxylate benzene sulphonate.

## Composition

Vespin (Amlodipine besylate) is available as oval-shaped tablets containing 5 mg and 10 mg Amlodipine (as besylate).

## Actions

Vespin (Amlodipine besylate) is a calcium ion influx inhibitor (slow channel blocker or calcium ion antagonist) and inhibits the transmembrane influx of calcium ions into cardiac and smooth muscles.

The mechanism of the antihypertensive action of Vespin (Amlodipine besylate) is due to a direct relaxant effect on vascular smooth muscle. The precise mechanism by which Vespin (Amlodipine besylate) relieves angina has not been fully determined but Vespin (Amlodipine besylate) reduces total ischemic burden by the following two actions:

1. Vespin (Amlodipine besylate) dilates peripheral arterioles thus, reduces the total peripheral resistance (after load) against which the heart works. Since there is no associated reflex tachycardia, this unloading of the heart reduces myocardial energy consumption and oxygen requirements and probably accounts for the effectiveness of Vespin (Amlodipine besylate) in myocardial ischemia.
2. The mechanism of action of Vespin (Amlodipine besylate) probably involves dilation of the main coronary arteries and coronary arterioles both in normal and ischemic regions. This dilation increases myocardial oxygen delivery in patients with coronary artery spasm (Prinzmetal's or variant angina).

After oral administration of therapeutic doses, Vespin (Amlodipine besylate) is well absorbed with peak blood levels between 6-12 hours postdose the volume of distribution is approximately 20 ltr/kg. The terminal plasma elimination half life is about 35-50 hours and is consistent with once daily dosing steady state plasma levels are reached after 7-8 days of consecutive dosing. Vespin (Amlodipine besylate) is extensively metabolised by the liver to inactive metabolites with 10% of the parent compound and 60% of metabolites excreted in the urine. In patients with hypertension once daily dosing provides clinically significant reduction of blood pressure in both the supine and standing positions throughout the 24 hours interval. Due to the slow onset of action, acute hypotension is not a feature of Vespin (Amlodipine besylate) administration.

In patients with angina, once daily administration of Vespin (Amlodipine besylate) increases total exercise time and decreases both angina attack frequency and nitroglycerine tablet consumption.

Vespin (Amlodipine besylate) has not been associated with any adverse metabolic effects or changes in plasma lipids and is suitable for use in patients with asthma, diabetes and gout.

In vitro studies have been shown that approximately 97.5% of circulating Vespin (Amlodipine besylate) is bound to plasma proteins.

## Drug Interactions

Vespin (Amlodipine besylate) has been safely administered with thiazide diuretics, beta blockers, angiotensin-converting enzyme inhibitors, long acting nitrates, sublingual nitroglycerine. Non-steroidal anti-inflammatory drugs, antibiotics and oral hypoglycemic drugs. Special studies have indicated that the co-administration of cimetidine did not alter the pharmacokinetics of Vespin (Amlodipine besylate).

In vitro data from studies with human plasma indicate that Vespin (Amlodipine besylate) has no effect on protein binding of the drugs tested (digoxin, phenytoin, warfarin or indomethacin).

## Indications

Vespin (Amlodipine besylate) is indicated for the first line treatment of hypertension and can be used as the sole agent to control blood pressure in the majority of patients. Patients not adequately controlled on a single antihypertensive agent may benefit from the addition of Vespin (Amlodipine besylate), which has been used in combination with a thiazide diuretic, beta adrenoceptor blocking agent, or an angiotensin-converting enzyme inhibitor.

Vespin (Amlodipine besylate) is indicated for the first line treatment of myocardial ischemia, whether due to fixed obstruction (stable angina) and/or vasospasm / vasoconstriction (Prinzmetal's or variant angina) of coronary vasculature.

Vespin (Amlodipine besylate) may be used when the clinical presentation suggests a possible vasospastic / vasoconstrictive component but where vasospasm / vasoconstriction has not been confirmed. Vespin (Amlodipine besylate) may be used alone, as monotherapy, or in combination with other antianginal drugs in patients with angina that is refractory to nitrates and / or adequate doses of beta blockers.

## Contraindications

Vespin (Amlodipine besylate) is contraindicated in patients with a known sensitivity to dihydropyridines.

## Warnings

### Use During Pregnancy and Lactation

Safety of Vespin (Amlodipine besylate) in human pregnancy or lactation has not been established. Vespin (Amlodipine besylate) does not demonstrate toxicity in animal reproductive studies other than to delayed parturition and prolonged labor in rats and a dose level fifty times the maximum recommended dose in humans. Accordingly, use in pregnancy is only recommended when there is no safer alternative and when the disease itself carries greater risk for the mother and child.

### Use in the Elderly

Although elderly patients may have higher plasma concentrations of Vespin (Amlodipine besylate) than those in the younger subjects, the terminal elimination half lives were similar. Vespin (Amlodipine besylate), used at similar doses in elderly or younger patients, is equally well tolerated. Therefore normal dosage regimens are recommended.

### Use in Renal Failure

Vespin (Amlodipine besylate) is extensively metabolised to inactive metabolites with 10% excreted as unchanged drug in the urine. Changes in Vespin (Amlodipine besylate) plasma concentrations are not correlated with degree of renal impairment. Vespin (Amlodipine besylate) may be used in such patients at normal doses. Vespin (Amlodipine besylate) is not dialysable.

### Use in Patients with Impaired Hepatic Function

Vespin (Amlodipine besylate) half-life is prolonged in patients with impaired liver function and dosage recommendations have not been established. The drug should therefore be administered with caution in these patients.

## Adverse Reactions

Vespin (Amlodipine besylate) is well tolerated. In placebo controlled clinical trials involving patients with hypertension or angina, the most commonly observed side effects were headache, edema, fatigue, nausea, flushing and dizziness. No pattern of clinically significant laboratory test abnormalities related to Vespin (Amlodipine besylate) has been observed.

## Dosage and Administration

For both hypertension and angina, the usual initial dose is 5 mg Vespin (Amlodipine besylate) once daily which may be increased to a maximum dose of 10 mg depending on the individual patient's response.

No dose adjustment for Vespin (Amlodipine besylate) is required upon concomitant administration of thiazide diuretics, beta blockers, and angiotensin-converting enzyme inhibitors.

## Over Dosage

There is no well documented experience with Vespin (Amlodipine besylate) overdosage. Since Vespin (Amlodipine besylate) absorption is slow, gastric lavage may be worthwhile in some cases. Available data suggests that gross overdosage could result in excessive peripheral vasodilation with subsequent marked and probably prolonged systemic hypotension. Clinically significant hypotension due to Vespin (Amlodipine besylate) 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 may be helpful in restoring vascular tone and blood pressure, provided that there is no contraindication to its use. Since Vespin (Amlodipine besylate) is highly protein-bound, dialysis is not likely to be of benefit.

## Packing

Vespin(Amlodipine as besylate) 5mg Tablets in 2 x 10's blister. Vespin(Amlodipine as besylate) 10mg Tablets in 2 x 10's blister.

## Caution :

- Store in a cool and dry place.
- Protect from light
- Keep out of the reach of children

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