

# Bisopro-A™ 2.5/5

Bisoprolol Fumarate 2.5 mg & Amlodipine 5 mg

## Presentation

Bisopro-A™ 2.5/5: Each tablet contains Bisoprolol Fumarate USP 2.5 mg & 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. Bisoprolol is cardioselective beta blocker without intrinsic sympathomimetic activity in its therapeutic dosage range. This combination allows increasing the antihypertensive and anti-anginal efficacy by complementary mechanism of actions of the two active compounds.

## Indications

Bisoprolol plus Amlodipine is indicated for the treatment of hypertension and angina. Bisoprolol plus Amlodipine is also indicated for the treatment of hypertension as substitution therapy in patients adequately controlled or not controlled with the individual products given concurrently at the same doses level as in the combination, but as separate tablets. It is also indicated for those patients with angina pectoris and hypertension as co-existing disease.

## Dosage and Administration

The usual starting dose is one tablet daily with or without food. If the desired therapeutic effect cannot be achieved, the dose may be increased. The dose however should be individualized.

## Side effects

Overall side effects include- headache, drowsiness, bradycardia, flushing, feeling of coldness and numbness, dyspnea, nausea, vomiting, diarrhea, constipation, abdominal pain, edema, fatigue and chest pain.

## Contraindications

Bisoprolol plus Amlodipine is contraindicated for patients with cardiogenic shock, high grade aortic stenosis, sinoatrial block, symptomatic bradycardia, symptomatic hypotension

## Precautions

Bronchospasm: The combination should be used with caution in patients with airway obstruction

For Renal Impairment: No dosage adjustment is required for patients with mild to moderate renal impairment. In case of severe renal impairment (creatinine clearance <20 mL/min), the daily dose must not exceed 10 mg.

For Hepatic Impairment: In case of severe hepatic impairment, the daily dose must not exceed 10 mg.

## Use in pregnancy and lactation

There are no adequate and well-controlled studies in pregnant women. This combination should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. This combination should be stopped during breastfeeding.

## Drug interactions

CYP3A4 Inhibitors: Concomitant use of amlodipine with strong or moderate inhibitors of CYP3A4 (e.g. protease inhibitors, verapamil or diltiazem) can be expected to increase the plasma concentrations of amlodipine. Insulin and Oral Antidiabetic Drugs: In combination with bisoprolol, intensification of blood sugar lowering effect may occur.

## Overdosage

The most common signs expected with overdose of Bisoprolol plus Amlodipine are bradycardia, hypotension, bronchospasm, acute cardiac insufficiency and hypoglycemia, peripheral vasodilatation and possibly reflex tachycardia.

## Storage

Store at temperature must not exceed 30°C.

## Commercial pack

Bisopro-A™ 2.5/5: Each box contains 3 blister strips of 10 tablets.