

# Tenobis-A

Bisoprolol Fumarate USP 2.5mg & Amlodipine USP 5mg

**Composition : Tenobis-A 2.5/5 :** Each tablet contains Bisoprolol Fumarate USP 2.5 mg & Amlodipine Besilate USP equivalent to Amlodipine 5 mg.

**Pharmacology :** Amlodipine is a Dihydropyridine Calcium antagonist that inhibit 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 product 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. Or, as directed by the registered physician.

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

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

**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.

**Use in Child :** There is no data available.

**Drug interaction :** 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.

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

**Storage :** Store below 30°C in a dry place.

**Packing : Tenobis-A 2.5/5 :** Each box contains 2 x 14's tablets in blister pack.



**DRUG INTERNATIONAL LTD.**

UNIT-3

31/1, SATRONG, TONGI I/A, GAZIPUR