

Bisocam™ 2.5/5

Bisoprolol + Amlodipine

COMPOSITION

Bisocam™ 2.5/5 Tablet: Each film coated tablet contains Bisoprolol Fumarate USP 2.5 mg and Amlodipine Besilate BP equivalent to Amlodipine 5 mg.

PHARMACOLOGY

Bisoprolol and Amlodipine combination increases the antihypertensive and anti-anginal efficacy by complementary mechanism of actions of the two active compounds: Vasoselective effect of the Amlodipine (decrease of peripheral resistance) and cardio selective beta-blocker Bisoprolol (decrease of cardiac output).

INDICATIONS

Bisoprolol & Amlodipine combination is indicated for the treatment of hypertension as substitution therapy in patients adequately controlled with the individual products given concurrently at the same doses level as in the combination, but as separate tablets.

DOSAGE & ADMINISTRATION

The recommended daily dose is one tablet with or without food. The dose may be increased if the desired therapeutic effect is not achieved.

CONTRAINDICATIONS

Bisoprolol & Amlodipine combination is contraindicated in patients with Acute heart failure, high grade aortic stenosis, cardiogenic shock, second or third degree AV block, Sick sinus syndrome, slowed heart rate, symptomatic bradycardia, symptomatic hypotension, severe bronchial asthma and hypersensitivity to Bisoprolol, Amlodipine or any of the excipients.

SIDE EFFECTS

Headache, drowsiness, dizziness, bradycardia.

OVER DOSAGE

The most common signs expected with overdose of Bisoprolol & Amlodipine are bradycardia, hypotension, bronchospasm, peripheral vasodilatation and reflex tachycardia.

DRUG INTERACTIONS

Centrally Acting Antihypertensive Drugs (e.g. Clonidine, Methyldopa, Moxonidine, Rilmenidine): Concomitant use of these drugs with Bisoprolol may lead to reduction of heart rate and cardiac output, as well as to vasodilation.

CYP3A4 Inhibitors: Concomitant use of amlodipine with strong or moderate inhibitors of CYP3A4 (e.g. protease inhibitors,azole antifungals, macrolides like erythromycin or clarithromycin, verapamil or Diltiazem) can be expected to increase the plasma concentrations of amlodipine to a clinically relevant extent.

Anesthetic Agents: In combination with Bisoprolol, the reflex tachycardia may be attenuated and the risk of hypotension may be increased.

Cardiac glycosides (Digitalis): Concomitant use with Bisoprolol may lead to a reduction of heart rate or an increase of atrio-ventricular conduction time.

USE IN PREGNANCY AND LACTATION

Pregnancy: Bisoprolol & Amlodipine combination is not recommended during pregnancy unless clearly necessary.

Nursing mothers: It is not known whether Bisoprolol or Amlodipine is excreted in human milk.

USE IN CHILDREN AND GERIATRIC PATIENTS

Children: Safety and effectiveness in paediatric patients have not been established.

Geriatric Patients: No dosage adjustment is required. However, caution is advised when the dose is increased.

STORAGE

Store below 30° C., protected from light & moisture. Keep out of the reach of children.

HOW SUPPLIED

Bisocam™ 2.5/5: Each box contains 3x10 tablets in alu-alu blister pack.

Manufactured by



TM-Trade Mark

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