# Bisocam<sup>™</sup>

Bisoprolol Fumarate + Amlodipine

# COMPOSITION

**Bisocam**<sup>™</sup> 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 β-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, bronchial asthma and hypersensitivity to Bisoprolol, Amlodipine or any of the excipients.

## SIDE EFFECTS

Headache, drowsiness, dizziness, bradycardia.

# **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.

## **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, 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.

## **OVER DOSAGE**

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

# STORAGE

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

## **HOW SUPPLIED**

**Bisocam**<sup>™</sup> 2.5/5: Each box contains 30 tablets in Alu-Alu blister pack.

Manufactured by

