Cardobis Plus®

Bisoprolol Fumarate USP and Hydrochlorothiazide BP Film Coated Tablet

DESCRIPTION

Cardobis Plus® is a combined preparation of Bisoprolol Fumarate & Hydrochlorothiazide. Bisoprolol Fumarate is a beta1-selective (cardioselective) adrenoceptor blocking agent without significant membrane stabilizing or intrinsic sympathomimetic activities in its therapeutic dose range. At higher doses (20 mg) Bisoprolol Fumarate also inhibits beta2-adrenoreceptors located in bronchial and vascular musculature. To retain relative selectivity, it is important to use the lowest effective dose. Hydrochlorothiazide is a benzothiadiazine diuretic. Thiazides affect renal tubular mechanisms of electrolyte reabsorption and increase excretion of sodium and chloride in approximately equivalent amounts.

INDICATIONS

Cardobis Plus® is indicated in the management of hypertension.

DOSAGE AND ADMINISTRATION

- **Initial Therapy:** Antihypertensive therapy may be initiated with the lowest dose of **Cardobis Plus**®, one 2.5/6.25 mg tablet once daily. Subsequent titration (14 day intervals) may be carried out with **Cardobis Plus**® tablets up to the maximum recommended dose 10/12.5 mg (two 5/6.25 mg tablets) once daily, as appropriate.
- **Replacement Therapy:** The combination may be substituted for the titrated individual components.
- **Cessation of Therapy:** If withdrawal of therapy is planned, it should be achieved gradually over a period of about 2 weeks. Patients should be carefully observed.

CONTRAINDICATIONS

Cardobis Plus® is contraindicated in patients with cardiogenic shock, overt cardiac failure, second or third degree AV block, marked sinus bradycardia, anuria and hypersensitivity to either component of this product or to other sulfonamide-derived drugs.

SIDE EFFECTS

- Bradycardia
- Arrhythmia
- Bronchospasm
- Fatigue

PRECAUTION AND WARNING

Although the probability of developing hypokalemia is reduced with Bisoprolol Fumarate & Hydrochlorothiazide because of the very low dose of Hydrochlorothiazide employed, periodic determination of serum electrolytes should be performed and patients should be observed for signs of fluid or electrolyte disturbances, i.e., hyponatremia, hypochloremic alkalosis and hypokalemia. Thiazides have been shown to increase the urinary excretion of magnesium; this may result in hypomagnesemia.

Calcium excretion is decreased by thiazides and pathologic changes in the parathyroid gland with hypercalcemia and hypophosphatemia have been observed in a few patients on prolonged thiazide therapy.

USE IN PREGNANCY AND LACTATION

Pregnancy Category C. There are no adequate and well-controlled studies with Bisoprolol Fumarate & Hydrochlorothiazide in pregnant women. Bisoprolol Fumarate & Hydrochlorothiazide should be used during pregnancy only if the potential benefit justifies the risk to the fetus.

PHARMACEUTICAL PRECAUTION

Store in a dry place, away from light. Keep out of reach of children.

PACKAGING

Cardobis Plus® 2.5/6.25 Tablet: Box containing 3 strips of 10 tablets each. Each film coated tablet contains Bisoprolol Fumarate USP 2.5 mg and Hydrochlorothiazide BP 6.25 mg.

Cardobis Plus® 5/6.25 Tablet: Box containing 3 strips of 10 tablets each. Each film coated tablet contains Bisoprolol Fumarate USP 5 mg and Hydrochlorothiazide BP 6.25 mg.

SK+F

Manufactured by

ESKAYEF BANGLADESH LIMITED

GAZIPUR, BANGLADESH

PM03459 V01