Cardobis®

Bisoprolol Fumarate USP Film Coated Tablet

DESCRIPTION

Cardobis® is a preparation of Bisoprolol Fumarate. Bisoprolol Fumarate is a beta1-selective (cardioselective) adrenoceptor blocking agent without significant membrane stabilizing activity or intrinsic sympathomimetic activity in its therapeutic dosage range. Cardioselectivity is not absolute, however, and at higher doses (>20 mg) Bisoprolol Fumarate also inhibits beta 2-adrenoceptors, chiefly located in the bronchial and vascular musculature; to retain selectivity it is therefore important to use the lowest effective dose.

INDICATIONS

Cardobis® (Bisoprolol Fumarate) is indicated in the management of hypertension. It may be used alone or in combination with other antihypertensive agents.

DOSAGE & ADMINISTRATION

- The dose of Bisoprolol Fumarate must be individualized to the needs of the patient. The usual starting dose is 5 mg once daily. In some patients, 1.25 mg may be an appropriate starting dose. If the antihypertensive effect of 5 mg is inadequate, the dose may be increased to 10 mg and then, if necessary, to 20 mg once daily.

- Patients with Renal or Hepatic Impairment: In patients with hepatic impairment (hepatitis or cirrhosis) or renal dysfunction (creatinine clearance less than 40 mL/min), the initial daily dose should be 2.5 mg and caution should be used in dose-titration.

- Geriatric Patients: It is not necessary to adjust the dose in the elderly, unless there is also significant renal or hepatic dysfunction.

CONTRAINDICATIONS

- Cardiogenic shock
- Overt cardiac failure
- Second or third degree AV block
- Marked sinus bradycardia

SIDE EFFECTS

- Bradycardia
- Diarrhea
- Asthenia
- Fatigue
- Sinusitis

PRECAUTION & WARNING

Patients, especially those with coronary artery disease, should be warned about discontinuing use of Bisoprolol Fumarate without a physician's supervision. Patients should also be advised to consult a physician if any difficulty in breathing occurs, or if they develop signs or symptoms of congestive heart failure or excessive bradycardia. Patients subject to spontaneous hypoglycemia or diabetic patients receiving insulin or oral hypoglycemic agents should be cautioned that beta-blockers may mask some of the manifestations of hypoglycemia, particularly tachycardia and Bisoprolol Fumarate should be used with caution. Patients should know how they react to this medicine before they operate automobiles and machinery or engage in other tasks requiring alertness.

USE IN PREGNANCY & LACTATION

Pregnancy Category C. There are no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Caution should be exercised when Bisoprolol Fumarate is administered to a nursing woman.

PHARMACEUTICAL PRECAUTION

Do not store above 30 °C temperature. Keep away from light and wet place. Keep out of reach of children.

PACKAGING

Cardobis® 1.25 FCT: Box containing 5 strips of 10 tablets each. Each Film Coated Tablet contains Bisoprolol Fumarate USP 1.25 mg.

Cardobis® 2.5 FCT: Box containing 5 strips of 10 tablets each. Each Film Coated Tablet contains Bisoprolol Fumarate USP 2.5 mg.

Cardobis® 5 FCT: Box containing 4 strips of 10 tablets each. Each Film Coated Tablet contains Bisoprolol Fumarate USP 5 mg.

SK+F

Manufactured by

ESKAYEF PHARMACEUTICALS LTD.

TONGI, GAZIPUR, BANGLADESH

PM06290 V04