Betabis™

Tablet

Bisoprolol Fumarate USP

COMPOSITION

Betabis™ 2.5: Each film-coated tablet contains Bisoprolol Fumarate USP 2.5 mg.
Betabis™ 5: Each film-coated tablet contains Bisoprolol Fumarate USP 5 mg.
Betabis™ 10: Each film-coated tablet contains Bisoprolol Fumarate USP 10 mg.

PHARMACOLOGY

Bisoprolol is the most potent β_1-selective β-blocker. It has the highest level of β_1-selectivity and by blocking the heart's β_1 adrenergic receptors it reduces heart rate & force of contraction of the heart and thus lowers blood pressure.

INDICATIONS

Betabis™ (Bisoprolol) is indicated in the management of hypertension, angina and heart failure. It may be used alone or in combination with other antihypertensive agents.

DOSAGE AND ADMINISTRATION

Route of Admininstration : Orally.
In Hypertension: The dose of **Betabis™** must be individualized to the needs of the patient. The usual starting dose is 5 mg once daily. In some patients, 2.5 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 <40 mL/min), the initial daily dose should be 2.5 mg and caution should be used in dose-titration. Since limited data suggest that Bisopolol is not dialyzable, drug replacement is not necessary in patients undergoing dialysis. **Geriatric Patients :** It is not necessary to adjust the dose in the elderly, unless there is also significant renal or hepatic dysfunction.
In Heart Failure: Initially 1.25 mg once daily (in the morning) for 1 week; then, if well tolerated, can be increased to 2.5 mg once daily for 1 week, then 3.75 mg once daily for 1 week, then 5 mg once daily for 4 weeks, then 7.5 mg once daily for 4 weeks, then 10 mg once daily; max. 10 mg daily.
OR AS DIRECTED BY THE PHYSICIAN.

CONTRAINDICATIONS

Bisoprolol is contraindicated in patients with cardiogenic shock, overt cardiac failure, second or third degree AV block, and marked sinus bradycardia.

WARNING & PRECAUTIONS

Impaired renal or hepatic function : Use with caution adjusting the dose of Bisoprolol in patients with renal or hepatic impairment.
Risk of anaphylactic reaction: While taking beta-blockers, patients with a history of severe anaphylactic reaction to a variety of allergens, caution should be exercised. Such patients may be unresponsive to the usual doses of epinephrine used to treat allergic reaction.

SIDE EFFECTS

Common side effects: Fatigue, dizziness, headache, sleep disturbance, bronchospasm, peripheral vasoconstriction, gastro-intestinal disturbances, bradycardia and worsening of heart failure.
Rare side effects: Less commonly depression, muscle weakness, cramp; rarely hypertriglyceridaemia, syncope, hearing impairment and very rarely conjunctivitis.

USE IN PREGNANCY & LACTATION

In Pregnancy:There are no adequate and well controlled studies of safety evidence in pregnant women. Therefore, Bisoprolol should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
In Lactation: It is not known whether this drug is excreted in human milk and therefore caution should be exercised when Bisoprolol is administered to nursing women.

USE IN CHILDREN & ADOLESCENTS

Safety and effectiveness have not been established in children.

DRUG INTERACTION

With Medicine: Bisoprolol should not be combined with other β-blocking agents. Patients receiving catecholamine-depleting drugs (e.g. Reserpine or Guanethidine) should be closely monitored. In patients receiving concurrent therapy with Clonidine, if therapy is to be discontinued, it is suggested that Bisoprolol be discontinued for several days before the withdrawal of Clonidine. Bisoprolol should be used with care when myocardial depressants or inhibitors of AV conduction, such as certain calcium antagonists (e.g. Verapamil, Diltiazem) or antiarrhythmic agents (e.g. Disopyramide) are used concurrently. Concurrent use of Rifampin increases the metabolic clearance of Bisoprolol resulting in a shortened elimination half-life of Bisoprolol.
With food & others: No interaction with foods.

OVERDOSE

The most common signs expected with overdose (max. 2000 mg) of a β-blocker are bradycardia, hypotension, congestive heart failure, bronchospasm and hypoglycemia.

STORAGE

Store below 30^0 C temperature & dry place, protected from light .
Keep all medicines out of reach of children.

PACKING

Betabis™ 2.5: Each box contains 3 X 10 tablets in Alu-Alu blister strips.
Betabis™ 5: Each box contains 3 X 10 tablets in Alu-Alu blister strips.
Betabis™ 10: Each box contains 3 X 10 tablets in Alu-Alu blister strips.

*** Further information is available on request.**

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Manufactured by:
The ACME Laboratories Ltd.
Dhulivita, Dhamrai, Dhaka, Bangladesh
For Health, Vigour and Happiness