Bisovik

Bisoprolol Fumarate BP

COMPOSITION:
Bisovik 2.5 Tablet: Each film coated tablet contains Bisoprolol Fumarate BP 2.5 mg.
Bisovik 5 Tablet: Each film coated tablet contains Bisoprolol Fumarate BP 5 mg.

PHARMACOLOGY:
Bisoprolol Fumarate is a selective beta-1 blocker. It selectively blocks beta-1 adrenergic receptor in the heart and vascular smooth muscle and reduces heart rate and cardiac output resulting in decrease of arterial hypertension.

PHARMACOKINETICS:
The absolute bioavailability after a 10 mg oral dose of Bisoprolol Fumarate is about 80%. Absorption is not affected by the presence of food. The first pass metabolism of Bisoprolol Fumarate is about 20%.

Binding to serum proteins is approximately 30%. Peak plasma concentration occurs within 2-4 hours of dosing with 5 to 20 mg and mean peak values range from 16 ng/ml at 5 mg to 70 ng/ml at 20 mg. The plasma elimination half-life is 9-12 hours and is slightly longer in elderly patients, in part because of decreased renal function in that population. Steady state is attained within 5 days of once daily dosing. In both young and elderly populations, plasma accumulation is low; the accumulation factor ranges from 1.1 to 1.3, and is what would be expected from the first order kinetics and once daily dosing. Plasma concentrations are proportional to the administered dose in the range of 5 to 20 mg. Pharmacokinetic characteristics of the two enantiomers are similar.

Bisoprolol Fumarate is eliminated equally by renal and non-renal pathways with about 50% of the dose appearing unchanged in the urine and the remainder appearing in the form of inactive metabolites. In humans, the known metabolites are labile or have no known pharmacologic activity. Less than 2% of the dose is excreted in the feces. Bisoprolol Fumarate is not metabolized by cytochrome CYP2D6 (debrisoquin hydroxylase). In subjects with creatinine clearance less than 40 ml/min, the plasma half-life is increased approximately threefold compared to healthy subjects.

In patients with cirrhosis of the liver, the elimination of Bisoprolol Fumarate is more variable in rate and significantly slower than that in healthy subjects, with plasma half-life ranging from 8.3 to 21.7 hours.

INDICATION :
Bisovik(Bisoprolol) is indicated in the management of hypertension and in the treatment of angina. It may be used alone or in combination with other antihypertensive agents.

DOSAGE & ADMINISTRATION:
The dose of Bisovik must be individualized to the needs of the patient. The usual starting dose is Bisovik 5 mg once daily. In some patients, Bisovik 2.5 mg may be an appropriate starting dose. If the antihypertensive effect of Bisovik 5 mg is inadequate, the dose may be increased to10 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 Bisoprolol Fumarate is not dialysable, drug replacement is not necessary in patients undergoing dialysis.

Geriatric Patients:
Bisoprolol Fumarate has been used in geriatric patients with hypertension. Although the resopnse rates & mean decrease in diastolic blood pressure were similar to that elderly patients, there is a tendency for older patients to be maintained on higher doses of Bisoprolol Fumarate.

Pediatric Patients:
Safety & effectiveness of Bisoprolol Fumarate in children have not been established.

CONTRAINDICATIONS:
Bisoprolol is contraindicated in patients with cardiogenic shock, overt cardiac failure, second or third degree A-V block, and marked sinus bradycardia.

SIDE EFFECTS:
Following are some of the side effects that are known to be associated with this medicine. The common side effects arefatigue, dizziness, headache, disturbances of the gut such as nausea, vomiting, diarrhoea, constipation or abdominal pain, cold or numb extremities, e.g. hands and feet, muscle weakness or cramps, slower than normal heart beat (bradycardia), worsening of heart failure, sleep disturbance, depression, breathing difficulties due to narrowing of the airways (bronchospasm) in people with asthma or COPD.

PRECAUTIONS:
Risk of anaphylactic reaction: While taking beta-blockers, patients with a history of severe anaphylactic reaction to a variety of allergens may be more reactive to repeated challenge, accidental, diagnostic or therapeutic. Such patients may be unresponsive to the usual doses of epinephrine used to treat allergic reaction.

USE IN PREGNANCY & LACTATION:
Pregnancy:
There are no studies in pregnant woman. Bisorpolol Fumarate should be used during pregnancy only if the potential benefit justifies the potential risk of the fetus.

Lactation:
It is not known whether this drug is excreted in human milk. If use of Bisoprolol Fumarate is considered essential, then mother should stop
nursing.

OVERDOSE:
The most common signs expected with overdosage of a beta-blocker are bradycardia, hypotension, congestive heart failure, bronchospasm and hypoglycemia. In general, if overdose occurs, Bisoprolol therapy should be stopped and supportive and symptomatic treatment should be provided.

STORAGE:
Store at a temperature of below 30ºC, protect from light & moisture. Keep out of the reach of children.

Packs:
Bisovik 2.5 Tablet: Each box contains 3x10's tablets in Alu-PVC blister pack.
Bisovik 5 Tablet: Each box contains 3x10's tablets in Alu-PVC blister pack.

Goodman
Manufactured by:
Goodman Pharmaceuticals Ltd.
Better Health For All
Bhangnahati, Sreepur, Gazipur, Bangladesh

Imported & Marketed by:
Al-Amin LTD