Bizolol®

Bisoprolol Fumarate USP

COMPOSITION
Bizolol® 2.5 Tablet: Each film coated tablet contains Bisoprolol Fumarate USP 2.5 mg.
Bizolol® 5 Tablet: Each film coated tablet contains Bisoprolol Fumarate USP 5 mg.

MECHANISM OF ACTION
Bisoprolol blocks the action of the sympathetic nervous system on the heart by blocking the heart's beta1-adrenergic receptors. Bisoprolol reduces the heart rate & force of contraction of the heart, thus lowers blood pressure.

PHARMACOKINETICS
Absorption: Rapid and almost complete.
Distribution: Widely; highest concentrations in heart, liver, lungs, and saliva.
Metabolism: Extensively hepatic; significant first-pass effect (~20%).
Excretion: Urine (50% as unchanged drug, remainder as inactive metabolites); feces (<2%).

INDICATION
Bizolol® (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 **Bizolol®** must be individualized to the needs of the patient. The usual starting dose is **Bizolol®** 5 mg once daily. In some patients, **Bizolol®** 2.5 mg may be an appropriate starting dose. If the antihypertensive effect of **Bizolol®** 5 mg is inadequate, the dose may be increased to **Bizolol®** 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 Bisoprolol fumarate 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.
Pediatric Patients: There is no pediatric experience with Bisoprolol.

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

USE IN PREGNANCY AND LACTATION
Pregnancy: Bisoprolol should not be used during pregnancy unless clearly necessary. If treatment with Bisoprolol is considered necessary, the uteroplacental blood flow and the foetal growth should be monitored.
In case of harmful effects on pregnancy or the foetus, alternative treatment should be considered. The newborn infant must be closely monitored. Symptoms of hypoglycaemia and bradycardia are generally to be expected within the first 3 days.
Lactation: It is not known whether this drug is excreted in human milk. Therefore, breast-feeding is not recommended during administration of Bisoprolol.

SIDE EFFECTS
Fatigue, 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 a narrowing of the airways (bronchospasm) in people with asthma or COPD.

PRECAUTION
Impaired renal or hepatic function: Use caution in 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 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.

OVERDOSAGE
The most common signs expected with overdosage of a beta-blocker are bradycardia, hypotension, congestive heart failure, bronchospasm, and hypoglycemia. Only a few cases of overdose with Bisoprolol have been reported. Bradycardia and/or hypotension were noted. Sympathomimetic agents were given in some cases, and all patients recovered. In general, if overdose occurs, Bisoprolol therapy should be stopped and supportive and symptomatic treatment should be provided.

STORAGE
Store below 30°C. Protect from light and moisture. Keep out of children's reach.

HOW SUPPLIED
Bizolol® 2.5 Tablet: Each box contains 30 tablets in blister pack.
Bizolol® 5 Tablet: Each box contains 30 tablets in blister pack.

SQUARE