# Bisoliv

Bisoprolol Fumarate USP

**Composition**
Bisoliv 2.5 Tablet: Each film coated tablet contains Bisoprolol Fumarate USP equivalent to Bisoprolol 2.5 mg.
Bisoliv 5 Tablet: Each film coated tablet contains Bisoprolol Fumarate USP equivalent to Bisoprolol 5 mg.

**Pharmacology**
Bisoprolol is a beta1-selective (cardioselective) adrenoceptor blocking agent without significant membrane stabilizing activity or intrinsic sympathomimetic activity in its therapeutic dosage range.

**Indication**
For the treatment of hypertension, angina and heart failure. It may be used alone or in combination with other antihypertensive agents.

**Dose & administration**
*a) Route of administration: Oral*
The dose of Bisoliv 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 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.

*For heart failure:* Initially 1.25 mg once daily (in the morning) for 1 week then, if well tolerated, 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.

**Contra-indication**
Patients with cardiogenic shock, overt cardiac failure, second or third degree AV block and marked sinus bradycardia.

**Warning and Precaution**
Impaired renal or hepatic function.

**Side effects**
*a) Common:* Diarrhoea, dizziness, drowsiness, fatigue, headache, lightheadedness, nausea, sleeplessness, unusual tiredness, weakness, Severe allergic reactions (rash, hives, itching, difficulty breathing, tightness in the chest, swelling of the mouth, face, lips, or tongue).
*b) Rare:* Chest pain, difficulty breathing, lightheadedness or dizziness when rising from a lying or sitting position, very slow heartbeat.

**Use in Pregnancy & Lactation**
Pregnancy Category C. There are no adequate and well-controlled studies in pregnant women. Bisoprolol should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
*Nursing Mothers:* Small amounts of bisoprolol fumarate (< 2% of the dose) have been detected in the milk of lactating rats. It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk caution should be exercised when bisoprolol fumarate is administered to nursing women.

**Use in Children & Adolescents**
See the dose and administration.

**Drug interaction**
*a) With medicine:* Bisoprolol should not be combined with other beta-blocking agents. Patients receiving catecholamine depleting drugs, should be closely monitored, because the added beta-adrenergic blocking action of Bisoprolol may produce excessive reduction of sympathetic activity. 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 or antiarrhythmic agents are used concurrently. Concomitant use with digitalis glycosides can increase the risk of bradycardia.Concurrent use of rifampin increases the metabolic clearance of Bisoprolol, resulting in a shortened elimination half-life of Bisoprolol. However, initial dose modification is generally not necessary.
*b) With food & others:* Bisoprolol interaction with food–It is important to know how to taka the medication to avoid the drug-food interaction. This interaction can sometimes also reduce the effectiveness of the drug itself.
*Salt substitute:* The combination of Bisoprolol with foods rich in salts like sodium, calcium and magnesium may reduce or negate the blood pressure-lowering effect of Bisoprolol.
*Potassium Rich Food:* Bisoprolol may increase the potassium levels in the blood. Avoid taking potassium rich food with Bisoprolol.
*Pleurisy Root:* Pleurisy root is not recommended with most heart medication due to the cardiac glycoside content of the root.

**Overdose**
The most common signs expected with overdosage of a beta-blocker are bradycardia, hypotension, congestive heart failure, bronchospasm, and hypoglycemia. To date, a few cases of overdose (maximum: 2000 mg) 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. Limited data suggest that bisoprolol fumarate is not dialyzable. Based on the expected pharmacologic actions and recommendations for other beta-blockers, the following general measures should be considered when clinically warranted.

**Storage**
Store below 30° C. Protect from light and moisture. Keep all medicines out of reach of children.

**Packing**
Bisoliv 2.5 Tablet: Each box contains 30 (3x10's) tablets in blister pack.
Bisoliv 5 Tablet: Each box contains 30 (3x10's) tablets in blister pack.

Manufactured by
**ONE PHARMA LTD.**
C-23-24, BSCIC I/A
Bogura, Bangladesh

LF0044 BSL Rev.03