SPMC

BISOPROLOL TABLETS BP 5 mg

PRESENTATION:
Bisoprolol Tablets BP 5 mg:
Pack sizes- 500 tablets & Blisters containing 200 Tablets. (20x10) Blisters

White colored 6.3 mm square film coated tablets. Each Tablet contains 5 mg of Bisoprolol fumarate**.**

MECHANISM OF ACTION:
Bisoprolol is a highly $beta_1$-selective-adrenoceptor blocking agent, lacking intrinsic stimulating and relevant membrane stabilising activity. It only shows low affinity to the $beta_2$-receptor of the smooth muscles of bronchi and vessels as well as to the $beta_2$-receptors concerned with metabolic regulation. Therefore, bisoprolol is generally not to be expected to influence the airway resistance and $beta_2$-mediated metabolic effects. Its $beta_1$-selectivity extends beyond the therapeutic dose range.

INDICATION AND DOSE:
Hypertension | Angina
Adult: 5–10 mg once daily; maximum 20 mg per day
Adjunct in heart failure
Adult: Initially 1.25 mg once daily for 1 week, dose to be taken in the morning, then increased if tolerated to 2.5 mg once daily for 1 week, then increased if Tolerated to 3.75 mg once daily for 1 week, then Increased if tolerated to 5 mg once daily for 4 weeks, then increased if tolerated to 7.5 mg once daily for 4 weeks, then increased if tolerated to 10 mg once Daily; maximum 10 mg per day

SPECIAL PATIENT GROUP:
Patients with bronchospastic disease: Initially, 2.5 mg once daily.

CONTRA INDICATIONS:
Cardiogenic and hypovolaemic shock, 2nd or 3rd degree atrioventricular block, sinoatrial block, sick sinus syndrome, symptomatic bradycardia and hypotension, untreated phaeochromocytoma, metabolic acidosis, severe peripheral arterial occlusive disease, severe Raynaud's syndrome, severe bronchial asthma or severe COPD, acute heart failure or during episodes of heart failure decompensation requiring IV inotropic therapy.

CAUTIONS:
Ensure heart failure not worsening before increasing dose insufficiency

SPECIAL PRECAUTIONS:
Patient with bronchospastic disease, myasthenia gravis, Raynaud's syndrome, diabetes mellitus, Prinzmetal's angina, 1st degree atrioventricular block, peripheral arterial occlusive disease, psoriasis, hyperthyroidism, hypoglycaemia. Patients undergoing major surgery involving general anaesthesia. Avoid abrupt withdrawal. Renal and hepatic impairment. Pregnancy and lactation.

SIDE EFFECTS:
Blood and lymphatic system disorders: Agranulocytosis, thrombocytopenia.
Cardiac disorders: Chest pain, bradycardia, palpitations.
Eye disorders: Ocular pain, visual disturbance.
Gastrointestinal disorders: Vomiting, constipation, diarrhoea, dry mouth, abdominal pain.
General disorders and admin site conditions: Asthenia, fatigue.
Musculoskeletal and connective tissue disorders: Gout, back pain, arthralgia.
Nervous system disorders: Dizziness, headache.
Respiratory, thoracic and mediastinal disorders: Dyspnoea, rhinitis, sinusitis.
Skin and subcutaneous tissue disorders: Rash, eczema, pruritus. Rarely, alopecia.
Vascular disorders: Syncope, cold or numb extremities, hypotension, flushing.

SIDE-EFFECTS, FURTHER INFORMATION:
Initial dosage in patients with cardiovascular disorders If metabolism increases too rapidly (causing diarrhoea, nervousness, rapid pulse, insomnia, tremors and sometimes anginal pain where there is latent myocardial ischaemia), reduce dose or withhold for 1–2 days and start again at a lower dose.

USE IN PREGNANCY:
Beta-blockers reduce placental perfusion, which may result in immature neonates or premature deliveries. Further adverse effects (especially hypoglycaemia and bradycardia) may occur in the foetus or neonate, and there is an increased risk of cardiac and pulmonary complications in the neonate during the postnatal period. In order to avoid complications in the neonate in the postnatal period (e.g., hypoglycaemia and bradycardia), the beta-blocker therapy should be discontinued 72 hours before the calculated term of delivery. If this is not possible, the neonate must be closely monitored. Symptoms of hypoglycaemia are generally expected within the first 3 days.

BREAST FEEDING:
It is unknown whether the drug is excreted in human milk. Therefore, breastfeeding is not recommended during administration of bisoprolol

HEPATIC IMPAIRMENT:
Manufacturer advises caution.
Dose adjustments-When used for angina or hypertension Manufacturer advises consider maximum dose of 10 mg once daily in severe impairment—consult product literature.
When used for heart failure Manufacturer advises caution when titrating dose (no information available).

RENAL IMPAIRMENT:
Dose adjustments When used for angina or hypertension gMax. 10mg daily if creatinine clearance less than 20 mL/minute. When used for heart failure gUse with caution when titrating dose (no information available).

INTERACTION:
May potentiate atrioventricular conduction time and may increase negative inotropic effect with class I antiarrhythmic drugs (e.g., quinidine, disopyramide, propafenone). Concomitant use with calcium antagonists (e.g., verapamil, diltiazem) may lead to atrioventricular block and profound hypotension. Concomitant catecholamine-depleting drugs (e.g., reserpine, guanethidine) may produce excessive reduction of sympathetic activity. Heart failure may worsen when given with centrally acting antihypertensives (e.g., clonidine, methyldopa). Increased risk of bradycardia with digitalis glycosides. Coadministration with rifampicin increases metabolic clearance of bisoprolol. Reduced hypotensive effect with NSAIDs.

FOOD INTERACTION:
Decreased bioavailability and lower serum levels with enteral nutrition. Reduced absorption with food, soybean infant formula, cottonseed meal, walnuts and dietary fiber.

ADMINISTRATION:
Should be taken on an empty stomach. Take 30 min-1 hr. before meals.

MONITORING PARAMETERS:
Monitor thyroid function test, clinical signs of hypo- and hyperthyroidism, heart rate and BP.

OVERDOSAGE:
Symptoms: Bradycardia, hypotension, bronchospasm, and hypoglycaemia.
Management: Symptomatic and supportive treatment. Administer IV atropine for bradycardia, if inadequate, isoproterenol may be given cautiously. IV fluids, vasopressors and IV glucagon should be administered for hypotension. Administer bronchodilator therapy (e.g. isoproterenol and/or aminophylline) for bronchospasm; and IV glucose for hypoglycaemia.

STORAGE:
Keep tightly closed in cool and dry place below 30°C. Store in the original package in order to protect from light and moisture.

Keep all medicines away from the reach of children

Manufactured by:
State Pharmaceuticals Manufacturing Corporation
No. 11, Sir John Kotalawala Mawatha, Kandawala Estate,
Ratmalana, Sri Lanka.