CORBIS-10

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only

Abbreviated Prescribing information for CORBIS-10 [Bisoprolol Fumarate Tablets I.P 10 mg]

[Please refer to the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

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.

INDICATIONS: For the treatment of hypertension, coronary heart disease (angina pectoris).

DOSAGE AND ADMINISTRATION: The usual adult dose is 10mg once daily with a maximum recommended dose of 20mg per day. In some patients, 5mg per day may be adequate. Bisoprolol tablet should be taken in the morning and can be taken with food. They should be swallowed in liquid and should not be chewed.

CONTRAINDICATION: acute heart failure or during episodes of heart failure decompensation requiring i.v. inotropic therapy, cardiogenic shock., sinoatrial block, second- or third-degree AV block (without pacemaker), bradycardia (heart rate less than 60 beats/min prior to start of therapy), severe bronchial asthma or severe chronic obstructive pulmonary disease, sick sinus syndrome, hypotension (systolic blood pressure <100mmHg), later stages of peripheral arterial occlusive disease and Raynaud's syndrome, untreated phaeochromocytoma, metabolic acidosis, hypersensitivity to the active substance(s) or to any of the excipients.

WARNINGS & PRECAUTIONS: In bronchial asthma or other chronic obstructive lung diseases, which may cause symptoms, bronchodilating therapy should be given concomitantly. Occasionally an increase of the airway resistance may occur in patients with asthma, therefore the dose of beta2-stimulants may have to be increased. concomitant treatment with inhalation anaesthetics, for patients with severe renal impairment and patients with severe liver function disorders, diabetes mellitus with large fluctuations in blood glucose values; symptoms of hypoglycaemia can be masked, strict fasting, ongoing desensitisation therapy, first degree AV block, prinzmetal's angina, peripheral arterial occlusive disease (intensification of complaints might happen especially during the start of therapy)

DRUG INTERACTIONS: Monoamine-oxidase inhibitors (except MAO-B inhibitors): Enhanced hypotensive effect of β-blockers but also risk of hypertensive crisis. Concomitant use of centrally acting antihypertensive drugs may further decrease the central sympathetic tonus (reduction of heart rate and cardiac output, vasodilation. Abrupt withdrawal, particularly if prior to beta-blocker discontinuation, may increase risk of “rebound hypertension”. The use of beta-blockers may intensify the blood sugar lowering effects of these drugs. Beta-blockers may also mask signs of hypoglycaemia, such as tachycardia. Combination with bisoprolol may unmask the alpha-adrenoceptor-mediated vasoconstrictor effects of these agents leading to blood pressure increase and exacerbated intermittent claudication. Such interactions are considered to be more likely with nonselective beta-blockers. Higher doses of adrenaline may be necessary for treatment of allergic reactions. Mefloquine: increased risk of bradycardia

ADVERSE REACTIONS: AV- condition disturbances, worsening of pre-existing heart failure, bradycardia, chest pain, feeling of coldness or numbness in the extremities, cyanosis of extremities, paraesthesia, Increased triglycerides. Beta-blockers may mask the symptoms of thyrotoxicosis or hypoglycaemia, If you already have Raynaud’s disease or intermittent claudication (pain in the legs while walking) Bisoprolol may make these worse, sleep disorders (including vivid dreams), depression, nightmares, hallucinations, anxiety, psychosis, confusion, tiredness, exhaustion, dizziness, headache, syncope, dry eyes (to be considered if the patient uses lenses), impaired vision, reduced tear flow, conjunctivitis, visual disturbances, hearing impairment, bronchospasm in patients with bronchial asthma or a history of obstructive airways disease, allergic rhinitis, nausea, vomiting, diarrhoea, constipation, increased liver enzymes (ALAT, ASAT),

hepatitis, perspiration, itching, flush, rash and angioedema, worsen psoriasis or induce psoriasis like rash, alopecia, muscular weakness, pain, cramps, muscle and joint ache, potency disorders, fatigue, oedema, asthenia.

MARKETED BY:

TORRENT PHARMA

Torrent Pharmaceuticals Limited.

IN/CORBIS-10 /JUN 2026/05/ABPI

(Additional information is available on request)