

CORBIS AM

For the use of a Registered Medical Practitioner or Hospital or a Laboratory only.

Abbreviated Prescribing information for CORBIS AM (Bisoprolol and Amlodipine Tablets)

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

PHARMACOLOGICAL PROPERTIES:

Mechanism of action: Bisoprolol is a highly beta₁-selective-adrenoceptor blocking agent, lacking intrinsic stimulating and relevant membrane stabilising activity. It only shows low affinity to the beta₂-receptor of the smooth muscles of bronchi and vessels as well as to the beta₂receptors concerned with metabolic regulation. Therefore, bisoprolol is generally not to be expected to influence the airway resistance and beta₂-mediated metabolic effects. Its beta₁selectivity extends beyond the therapeutic dose range.

DOSAGE AND ADMINISTRATION: As directed by physician.

CONTRAINDICATION: Bisoprolol and Amlodipine is contraindicated in chronic heart failure patients with: Acute heart failure or during episodes of heart failure decompensation requiring i.v. inotropic therapy, Cardiogenic shock, Second or third degree AV block, Sick sinus syndrome, Sinoatrial block, Symptomatic bradycardia, Symptomatic hypotension, Severe bronchial asthma, Severe forms of peripheral arterial occlusive disease or severe forms of Raynaud's syndrome, Untreated phaeochromocytoma, Metabolic acidosis, Hypersensitivity to bisoprolol dihydropyridine derivatives, amlodipine or to any of the excipients listed, Severe hypotension, Shock (including cardiogenic shock), Obstruction of the outflow tract of the left ventricle (e.g., high grade aortic stenosis), Haemodynamically unstable heart failure after acute myocardial infarction.

WARNINGS & PRECAUTIONS: Bisoprolol Fumarate: Bisoprolol must be used with caution in: Bronchospasm (bronchial asthma, obstructive airways diseases), Diabetes mellitus with large fluctuations in blood glucose values; Symptoms of hypoglycaemia can be masked, Strict fasting, Ongoing desensitisation therapy. As with other beta-blockers, bisoprolol may increase both the sensitivity towards allergens and the severity of anaphylactic reactions. Epinephrine treatment does not always yield the expected therapeutic effect, First degree AV block, Prinzmetal's angina, Peripheral arterial occlusive disease. Aggravation of symptoms may occur especially when starting therapy and General anaesthesia **Amlodipine Besylate:** Patients with cardiac failure, Patients with hepatic impairment, Elderly patients, Patients with renal impairment

DRUG INTERACTION: Combinations not recommended with Calcium antagonists of the verapamil type and to a lesser extent of the diltiazem type Class I antiarrhythmic drugs, Centrally acting antihypertensive drugs. **Combinations to be used with caution** with Class-III antiarrhythmic drugs, Topical beta-blockers, Parasympathomimetic drugs, Insulin and oral antidiabetic drugs, Anaesthetic agents, Digitalis glycosides, NSAIDs, β-Sympathomimetic agents, Sympathomimetics that activate both β- and α-adrenoceptors, Concomitant use with antihypertensive agents as well as with other drugs with blood pressure lowering potential, Mefloquine, Monoamine oxidase inhibitors (except MAO-B inhibitors). **Amlodipine Besylate** Effects of other medicinal products on amlodipine: CYP3A4 inhibitors, CYP3A4 inducers, Dantrolene (infusion), Effects of amlodipine on other medicinal products, Tacrolimus, Cyclosporine, Simvastatin

ADVERSE REACTIONS: Bradycardia, worsening of heart failure, AV-conduction disturbances, increased triglycerides, increased liver enzymes (ALAT, ASAT), dizziness,

headache, syncope, reduced tear flow (to be considered if the patient uses lenses), conjunctivitis, hearing disorders, bronchospasm in patients with bronchial asthma or a history of obstructive airways disease, allergic rhinitis, gastrointestinal complaints such as nausea, vomiting, diarrhoea, hypersensitivity reactions (itching, flush, rash), alopecia. Beta-blockers may provoke or worsen psoriasis or induce psoriasis-like rash, muscular weakness and cramps, feeling of coldness or numbness in the extremities, hypotension, orthostatic hypotension, asthenia, fatigue, hepatitis, potency disorders, erectile dysfunction, sleep disorders, depression, nightmares, hallucinations.

Manufactured by:

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IN/ CORBIS AM 2.5/5mg, 5/5 mg/APR-21/01/ABPI

(Additional information is available on request)