CORBIS AM 2.5/2.5 CORBIS AM 2.5/5

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

Abbreviated Prescribing information for CORBIS AM 2.5/2.5 CORBIS AM 2.5/5[Amlodipine and Bisoprolol Fumarate Tablets (2.5mg + 2.5mg & 2.5mg + 5mg)]

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

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: ***Amlodipine-*** Amlodipine is a calcium ion influx inhibitor of the dihydropyridine group (slow channel blocker or calcium ion antagonist) and inhibits the transmembrane influx of calcium ions into cardiac and vascular smooth muscle. The mechanism of the antihypertensive action of amlodipine is due to a direct relaxant effect on vascular smooth muscle. ***Bisoprolol-*** Bisoprolol is a potent, highly 1-selective adrenoreceptor-blocking agent devoid of intrinsic sympathomimetic activity (ISA) and without relevant membrane stabilising activity. Antihypertensive effect of beta-blockers is among others due to decrease of renin activity.

INDICATION: For the treatment of mild to moderate hypertension.

DOSAGE AND ADMINISTRATION: Recommended daily dose is one tablet of the given strength. Amlodipine and Bisoprolol Fumarate tablet should be taken in the morning with or without food, without chewing it.

CONTRAINDICATION: ***Amlodipine-*** 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. ***Bisoprolol-*** Acute heart failure or during episodes of heart failure decompensation requiring I.V. inotropic therapy, cardiogenic shock, second- or third-degree AV block (without a pacemaker), sick sinus syndrome, sinoatrial block, symptomatic bradycardia, symptomatic hypotension, severe bronchial asthma, severe forms of peripheral arterial occlusive disease and severe forms of Raynaud's syndrome, untreated phaeochromocytoma, metabolic acidosis, Hypersensitivity.

WARNINGS & PRECAUTIONS: ***Amlodipine-*** Calcium channel blockers, including amlodipine, should be used with caution in patients with congestive heart failure, as they may increase the risk of future cardiovascular events and mortality. Amlodipine should therefore be administered with caution in these patients. Careful monitoring may be required in patients with severe hepatic impairment. Changes in amlodipine plasma concentrations are not correlated with degree of renal impairment. ***Bisoprolol-*** Patients suffering from ischaemic heart disease the cessation of therapy with bisoprolol must not be done abruptly unless clearly indicated, as it may lead to temporary deterioration of heart disease. Bisoprolol must be used with caution in diabetes mellitus, first degree av block, prinzmetal's angina, Peripheral arterial occlusive disease, phaeochromocytoma. If it is thought necessary to withdraw beta-blocker therapy before surgery, this should be done gradually and completed about 48 hours before anaesthesia.

DRUG INTERACTIONS: ***Amlodipine-*** Concomitant use of amlodipine with strong or moderate inhibitors of CYP3A4 (e.g. protease inhibitors like indinavir, saquinavir and ritonavir, azole antifungals such as fluconazole and itraconazole, macrolides like erythromycin or clarithromycin, verapamil or diltiazem) may give rise to significant increase in amlodipine exposure resulting in an increased risk of hypotension. Due to risk of hyperkalemia, it is recommended that the co-administration of calcium channel blockers such as amlodipine be avoided in patients susceptible to malignant hyperthermia and in the management of malignant hyperthermia. In order to avoid toxicity of tacrolimus, administration of amlodipine in a patient treated with tacrolimus requires monitoring of tacrolimus blood levels and dose adjustment of tacrolimus when appropriate. ***Bisoprolol-*** Concomitant use of centrally acting antihypertensive drugs may lead to reduction of heart rate and cardiac output and vasodilation. Abrupt withdrawal of the drug may increase the risk of "rebound hypertension". Combination with bisoprolol may unmask the alpha-adrenoceptor-mediated vasoconstrictor effects of these agents leading to blood pressure increase. Such interactions are considered to be more likely with nonselective beta-blockers.

ADVERSE REACTIONS: oedema, fatigue, asthenia, chest pain, pain, malaise somnolence, dizziness, headache, tremor, dysgeusia, syncope, hypoaesthesia, paraesthesia hypertonia, peripheral neuropathy depression, mood changes (including anxiety), insomnia, confusion, visual disturbances (including diplopia), tinnitus, palpitation, arrhythmia, myocardial infarction, flushing, hypotension, vasculitis dyspnoea, cough, rhinitis, abdominal pain, nausea, dyspepsia, altered bowel habits, vomiting, dry mouth, pancreatitis, gastritis, gingival hyperplasia, hepatitis, jaundice, hepatic enzyme increase, alopecia, prupura, skin discolouration, hyperhidrosis, pruritus, rash, exanthema, urticaria, angioedema, erythema multiforme, exfoliative dermatitis, steven's johnson syndrome, quincke oedema, photosensitivity, ankle swelling, muscle cramps, arthalgia, myalgia, back pain, micturation disorder, nycturia, increased urinary frequency, impotence, gynecomastia, leukopenia, thrombocytopenia, allergic reactions, hyperglycaemia, extrapyramidal syndrome, elevated triglyceride levels, depression, sleep disorders, nightmares, hallucinations, dizziness, syncope, decreased tear secretion, conjunctivitis, hearing impairments av-conduction disorders, deterioration of preexisting heart failure, bradycardia, feeling of coldness and numbness in the extremities, bronchospasm in patients with bronchial asthma or a history of obstructive pulmonary disease, constipation, beta-blockers can provoke or aggravate psoriasis or cause psoriasis-like skin disorder.

MARKETED BY

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