BETACARD H

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

Abbreviated Prescribing information for **BETACARD H** [Atenolol 50mg and Hydrochlorothiazide 12.5mg Tablet] [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: **Atenolol** is a β1-selective (cardioselective) beta-adrenergic receptor blocking agent without membrane stabilizing or intrinsic sympathomimetic (partial agonist) activities. **Hydrochlorothiazide** is a thiazide diuretic **INDICATION**: Betacard-H is indicated for the management of hypertension. **DOSAGE AND ADMINISTRATION**: **Atenolol:** Dosage must be individualized. Dosages should be determined by individual titration, dosages may be increased gradually until optimum blood pressure achieved. Atenolol is usually given at a dosage of 25 to 100 mg per day. **Hydrochlorothiazide** is usually given at a dosage of 12.5 to 50mg per day. Some patients will respond to doses of 12.5mg daily. Doses >25mg daily often lower BP only slightly more than doses 25mg (i.e. a relatively flat dose response). **CONTRAINDICATION:** Contraindicated in patients with cardiogenic shock, uncontrolled heart failure, sick sinus syndrome, second-or third-degree heart block, untreated phaeochromocytoma, metabolic acidosis, bradycardia (<45 bpm), hypotension, severe peripheral arterial circulatory disturbances, anuria and hypersensitivity to the active ingredient. **WARNINGS & PRECAUTIONS**: **Atenolol:** Cessation of therapy with atenolol patients with coronary artery disease, who are being treated with atenolol, should be advised against abrupt discontinuation of therapy. Use cautiously and stop the atenolol in patient with cardiac failure, without history of cardiac failure (continued depression of the myocardium with β-blocking agents over a period of time), hepatic insufficiency, diabetes and hypoglycemia, bronchospastic diseases, thyrotoxicosis, untreated pheochromocytoma, concomitant use of calcium channel blockers, anesthesia and major surgery, pregnancy and fetal injury and impaired renal function. **Hydrochlorothiazide:** Use cautiously and stop the hydrochlorothiazide in patient with hepatic impairment, hypersensitivity reaction, systemic lupus erythematosus, lithium interaction, acute myopia and secondary angle-closure glaucoma, possible electrolyte imbalance and impaired renal function.

DRUG INTERACTIONS: **Atenolol:** Catecholamine-depleting drugs (eg, reserpine), Calcium channel blockers, disopyramide, amiodarone, prostaglandin synthase inhibiting drugs, eg, indomethacin and digitalis glycosides. **Hydrochlorothiazide:** Alcohol, barbiturates, or narcotics, antidiabetic drugs (oral agents and insulin), other antihypertensive drugs, cholestyramine and colestipol resins, corticosteroids, ACTH, pressor amines (e.g., norepinephrine), skeletal muscle relaxants, nondepolarizing (e.g., tubocurarine), lithium, NSAIDS, digitalis glycosides, metformin, probenecid, sulfinpyrazone and allopurinol, calcium salts, beta-blockers and diazoxide, amantadine and cytotoxic agents (e.g. cyclophosphamide, methotrexate)

ADVERSE REACTIONS: Bradycardia, cold extremities, gastrointestinal disturbances, nausea, diarhhoea, fatigue, leg pain, lethargy, combined with aching and sore throat, agranulocytosis, reversible mental depression progressing to catatonia, mesenteric arterial thrombosis, erythematous rash, thrombocytopenia, mood changes, confusion, psychoses and hallucinations, depression, dreaming, dizziness, headache, vertigo, light-headedness, drowsiness, dry eyes, postural hypotension, in susceptible patients raynaud's phenomenon, heart failure deterioration, precipitation of heart block, bronchospasm may occur in patients with bronchial asthma, dry mouth, hepatic toxicity including intrahepatic cholestasis, alopecia, psoriasis, exacerbation of psoriasis and impotence. Weakness, pancreatitis, jaundice, sialadenitis, cramping, gastric irritation, aplastic anemia, leukopenia, hemolytic anemia, photosensitivity, urticaria, necrotizing angiitis, fever, respiratory distress including pneumonitis and pulmonary edema, anaphylactic reactions, hyperglycemia, glycosuria, hyperuricemia, muscle spasm, restlessness, renal failure, renal dysfunction, interstitial nephritis, erythema multiforme including Stevens-Johnson syndrome, exfoliative dermatitis including toxic epidermal necrolysis,

transient blurred vision, xanthopsia, impotence, bronchitis, pharyngitis, sinusitis, sleep disorder, visual disturbances, hyperhidrosis, limb pain, Influenza-like illness and creatinine phosphokinase increased.

MARKETED BY:

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IN/BETACARD H 50,12.5mg/AUG-2015/01/ABPI
(Additional information is available on request)