LOSAR BETA-H

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

Abbreviated Prescribing information for LOSAR BETA-H (Losartan Potassium, Atenolol and Hydrochlorothiazide Tablets**)**

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

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: Losartan is oral angiotensin-II receptor (type AT_1) antagonist. Angiotensin II, a potent vasoconstrictor, is the primary active hormone of the RAS. Angiotensin II also stimulates smooth-muscle cell proliferation. Atenolol is a beta-blocker, which is $beta_1$-selective. Thiazides affect the renal tubular mechanisms of electrolyte reabsorption, directly increasing excretion of sodium and chloride in approximately equivalent amounts. The diuretic action of hydrochlorothiazide reduces plasma volume, increases plasma renin activity and increases aldosterone secretion, with consequent increases in urinary potassium and bicarbonate loss, and decreases in serum potassium.

INDICATION: For the treatment of hypertension.

DOSAGE AND ADMINISTRATION: As directed by Physician.

CONTRAINDICATION: Hypersensitivity to losartan, sulphonamide-derived substances (as hydrochlorothiazide), active substance, to any of the excipients or any other ACE (Angiotensin Converting Enzyme) inhibitors or to any of the excipients, Therapy resistant hypokalaemia or hypercalcaemia, Severe hepatic impairment; cholestasis and biliary obstructive disorders, Refractory hyponatraemia, Symptomatic hyperuricaemia/gout, 2nd and 3rd trimester of pregnancy, Severe renal impairment (i.e. creatinine clearance <30 ml/min), Anuria, concomitant use of Losartan Potassium, Atenolol and Hydrochlorothiazide Tablets with aliskiren-containing products is contraindicated in patients with diabetes mellitus or renal impairment (GFR < 60 ml/min/1.73 m^2), Cardiogenic shock, Uncontrolled heart failure, Sick sinus syndrome (including sino-atrial block), Second-or third-degree heart block, Untreated phaeochromocytoma, Metabolic acidosis, Bradycardia, Hypotension, Severe peripheral arterial circulatory disturbances, Severe asthma and severe chronic obstructive pulmonary disorders, intravenous application of calcium channel blockers is contraindicated who use atenolol.

WARNINGS & PRECAUTIONS: *Losartan:* Angioedema, Hypotension and Intravascular volume depletion, Electrolyte imbalances, Liver and renal function impairment, Renal transplantation, Primary hyperaldosteronism, Heart failure, aortic and mitral valve stenosis, obstructive hypertrophic cardiomyopathy, Ethnic differences, pregnancy, dual blockade of the RAAS. *Atenolol as with other beta-blockers:* Should not be withdrawn abruptly, increase the number and duration of angina attacks in patients with Prinzmetal's angina, severe peripheral arterial circulatory disturbances, negative effect on conduction time, caution must be exercised, with first-degree heart block, mask the symptoms of hypoglycaemia, thyrotoxicosis, reduce heart rate, angioedema and urticarial, all beta-blockers should be avoided with reversible obstructive airways disease, excreted via the kidneys, dosage should be reduced in patients with a creatinine clearance, in patients with a phaeochromocytoma, anamnestically known psoriasis. *Hydrochlorothiazide:* Hypotension and electrolyte/fluid imbalance, Metabolic and endocrine effects, Hepatic impairment, Non-melanoma skin cancer.

DRUG INTERACTION: *Losartan*: Rifampicin and fluconazole reduces levels of active metabolite, potassium-sparing diuretics (e.g. spironolactone, triamterene, amiloride), potassium supplements, or salt substitutes containing potassium increases in serum potassium. Co-medication is not advisable; products which affect the excretion of sodium, lithium excretion reduced. Tricyclic antidepressants, antipsychotics, baclofen, and amifostine: Concomitant use with products that lower blood pressure, may increase the risk of hypotension. *Atenolol:* Combined use of beta-blockers and calcium channel blockers with negative inotropic effects, e.g. verapamil and diltiazem, can lead to an exaggeration, Concomitant therapy with dihydropyridines, e.g. nifedipine, increases the risk of hypotension, and cardiac failure, Digitalis glycosides increase atrioventricular conduction time, Caution must be exercised with a beta-blocker with Class I antiarrhythmic agents, sympathomimetic agents, e.g. adrenaline (epinephrine), insulin and oral antidiabetic drugs, prostaglandin synthetase-inhibiting drugs, anaesthetic agents. Not

recommended with monoamineoxidase inhibitors, Baclofen, contrast media, iodinated, Amiodarone, Ampicillin, Peripheral muscle relaxants. Hydrochlorothiazide: Alcohol, barbiturates, narcotics or antidepressants, Antidiabetic medicinal products, Cholestyramine and colestipol resins, Corticosteroids, ACTH, Pressor amines (e.g. adrenaline), Skeletal muscle relaxants, non-depolarizing (e.g. tubocurarine), Lithium, probenecid, sulfinpyrazone and allopurinol, Anticholinergic agents, Cytotoxic agents, Salicylates, Methyldopa, Cyclosporin, Digitalis glycosides, Medicinal products affected by serum potassium disturbances, Calcium salts, Carbamazepine, Iodine Contrast Media, Amphotericin B (parenteral), corticosteroids, ACTH, stimulant laxatives, or glycyrrhizin (found in liquorice).

ADVERSE REACTIONS: Hepatitis, Hyperkalaemia, anaemia, Henoch-Schönlein purpura, ecchymosis, haemolysis, thrombocytopenia, hypotension, orthostatic hypotension, sternalgia, angina pectoris, grade II-AV block, cerebrovascular event, myocardial infarction, palpitation, arrhythmias, vertigo, tinnitus, blurred vision, burning/stinging in the eye, conjunctivitis, decrease in visual acuity, abdominal pain, dyspepsia, constipation, dental pain, dry mouth, flatulence, gastritis, vomiting, obstipation, pancreatitis, asthenia, fatigue, chest pain, facial oedema, oedema, fever, flu-like symptoms, malaise, liver function abnormalities, hypersensitivity, anorexia, gout, muscle cramp, back pain, leg pain, myalgia, arm pain, joint swelling, knee pain, musculoskeletal pain, shoulder pain, stiffness, arthralgia, arthritis, coxalgia, fibromyalgia, muscle weakness, rhabdomyolysis, headache, dizziness, nervousness, paraesthesia, peripheral neuropathy, tremor, migraine, syncope, dysgeusia, insomnia, anxiety, anxiety disorder, panic disorder, confusion, depression, abnormal dreams, sleep disorder, somnolence, memory impairment, renal impairment and failure, nocturia, urinary frequency, urinary tract infection, decreased libido, erectile dysfunction/impotence, cough, upper respiratory infection, nasal congestion, sinusitis, sinus disorder, pharyngeal discomfort, pharyngitis, laryngitis, dyspnoea, bronchitis, epistaxis, rhinitis, respiratory congestion, alopecia, dermatitis, dry skin, erythema, flushing, photosensitivity, pruritus, rash, urticaria, sweating, vasculitis, hyperkalaemia, mild reduction of haematocrit and haemoglobin, hypoglycaemia, hyponatraemia, Purpura, thrombocytopenia, leucopenia, Mood changes, depression, anxiety, nightmares, confusion, psychoses and hallucinations, Dry eyes, impaired vision, visual disturbances, Bradycardia, Cold extremities, Alopecia, psoriasiform skin reactions, exacerbation of psoriasis, skin rashes, Lupus like syndrome, Fatigue, sweating, Agranulocytosis, aplastic anaemia, haemolytic anaemia, leukopenia, purpura, thrombocytopenia, Cephalalgia, Transient blurred vision, xanthopsia, Icterus (intrahepatic cholestatis), Muscle cramps, Fever, dizziness, Glycosuria, interstitial nephritis, renal dysfunction, renal failure, pneumonitis and pulmonary oedema, Anaphylactic reaction.

MARKETED BY

TORRENT PHARMA

TORRENT PHARMACEUTICALS LTD.

IN/LOSAR BETA-H 50, 50, 12.5 mg /FEB-26/02/ABPI

(Additional information is available on request)