TOZAAR H

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

Abbreviated Prescribing information for Tozaar H (Losartan Potassium I.P. 50mg and Hydrochlorothiazide tablets I.P. 12.5mg) [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Losartan: Losartan potassium is an angiotensin II receptor (type AT1) antagonist. **Hydrochlorothiazide:** Hydrochlorothiazide is a thiazide diuretic.

INDICATION: For treatment of mild to moderate hypertension.

DOSAGE AND ADMINISTRATION: Hypertension: Once or twice daily at total daily doses of 25 to 100 mg. Hydrochlorothiazide is effective in doses of 12.5 to 50 mg once daily and can be given at doses of 12.5 to 25 mg as losartan + HCTZ. Dose Titration by Clinical Effect: A patient whose blood pressure is not adequately controlled with losartan monotherapy or hydrochlorothiazide alone may be switched to losartan + HCTZ 50-12.5 once daily. Use in Patients with Renal Impairment: In patients with more severe renal impairment, losartan + HCTZ is not recommended. Patients with Hepatic Impairment: Losartan + HCTZ are not recommended for titration in patients with hepatic impairment. Severe Hypertension: Initial treatment of severe hypertension is one tablet of losartan + HCTZ 50- 12.5 once daily. The maximum dose is one tablet of losartan + HCTZ 100-25 once daily. Hypertensive Patients with Left Ventricular Hypertrophy: losartan + HCTZ 50-12.5

CONTRINDICATIONS: In patients who are hypersensitive to any component of this product. Patients with anuria or hypersensitivity to other sulfonamide-derived drugs. Do not co-administer aliskiren with Losartan and hydrochlorothiazide in patients with diabetes.

WARNINGS & PRECAUTIONS: Losartan: Fetal Toxicity (include skull hypoplasia, anuria, hypotension, renal failure, and death), Hypotension — Volume-Depleted Patients, losartan and hydrochlorothiazide is not recommended for patients with hepatic impairment.

Hydrochlorothiazide: Caution in patients with impaired hepatic function or progressive liver disease, Hypersensitivity reactions, Systemic Lupus Erythematosus, Lithium Interaction, Acute Myopia and Secondary Angle-Closure Glaucoma, Angioedema, fluid or electrolyte imbalance, Hypokalemia, Hyperuricemia, Hyperglycemia, Increases in cholesterol and triglyceride levels.

DRUG INTERACTION: Rifampicin, fluconazole, spironolactone, triamterene, amiloride, nsaids, tricyclic antidepressants, antipsychotics, baclofene, amifostine, alcohol, barbiturates, narcotics or antidepressants, antidiabetic drugs, cholestyramine and colestipol resins, corticosteroids, ACTH, pressor amines (e.g. adrenaline), skeletal muscle relaxants, nondepolarizing (e.g. tubocurarine), lithium, probenecid, sulfinpyrazone and allopurinol, anticholinergic agents (e.g. atropine, biperiden), cytotoxic agents (e.g. cyclophosphamide, methotrexate), salicylates, methyldopa, cyclosporin, digitalis glycosides, quinidine, hydroquinidine, disopyramide, amiodarone, sotalol, dofetilide, ibutilide, thioridazine, chlorpromazine, levomepromazine, trifluoperazine, haloperidol and carbamazepine.

ADVERSE REACTIONS: hepatitis, hyperkalaemia, elevation of alt, anaemia, henoch-schönlein purpura, ecchymosis, haemolysis, thrombocytopenia, hypotension, orthostatic hypotension, angina pectoris, grade ii-av block, cerebrovascular event, myocardial infarction, palpitation, arrhythmias (atrial fibrillations, sinus bradycardia, tachycardia ventricular tachycardia, ventricular fibrillation), vertigo, tinnitus, blurred vision, burning/stinging in the eye, conjunctivitis, decrease in visual acuity, abdominal pain, nausea, diarrhea, dyspepsia, constipation, dental pain, dry mouth, flatulence, gastritis, vomiting, obstipation, pancreatitis, asthenia, fatigue, chest pain, facial oedema, oedema, fever, flu-like symptoms, malaise, anorexia, gout, muscle cramp, back pain, leg pain, myalgia, arm pain, joint swelling, knee pain, musculoskeletal pain, shoulder pain, stiffness, arthralgia, arthritis,

fibromyalgia, muscle weakness, rhabdomyolysis, headache, dizziness, nervousness, paraesthesia, peripheral neuropathy, tremor, migraine, syncope, dysgeusia, insomnia, anxiety, panic disorder, confusion, depression, abnormal dreams, sleep disorder, somnolence, memory impairment, renal impairment, renal failure, nocturia, urinary frequency, urinary tract infection, decreased libido, erectile dysfunction/impotence, cough, upper respiratory infection, nasal congestion, sinusitis, sinus disorder, pharyngitis, laryngitis, dyspnoea, bronchitis, epistaxis, rhinitis, respiratory congestion, alopecia, dermatitis, dry skin, erythema, flushing, photosensitivity, pruritus, rash, sweating, vasculitis, dose-related orthostatic effects, hyperkalaemia, mild reduction of haematocrit and haemoglobin, hypoglycaemia, mild increase in urea and creatinine serum levels, agranulocytosis, aplastic anaemia, haemolytic anaemia, leukopenia, purpura, thrombocytopenia, anorexia, hyperglycaemia, hyperuricaemia, hypokalaemia, transient blurred vision, xanthopsia, necrotizing angiitis (vasculitis, cutaneous vasculitis), respiratory distress including pneumonitis and pulmonary oedema, sialoadenitis, spasms, stomach irritation, nausea, vomiting, diarrhoea, constipation, icterus (intrahepatic cholestatis), pancreatitis, photosensitivity, urticaria, toxic epidermal necrolysis, muscle cramps, glycosuria, interstitial nephritis, renal dysfunction, renal failure, fever and dizziness.

MARKETED BY:

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(Additional information is available on request)