TOZAAR 25/50

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

Abbreviated Prescribing information for Tozaar 25/50 (Losartan Potassium Tablets I.P.) [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Losartan potassium is an angiotensin II receptor (type AT1) antagonist. **INDICATION:** In the treatment of mild to moderate hypertension. **DOSAGE AND ADMINISTRATION:** Losartan can be administered once or twice daily with total daily doses ranging from 25 mg to 100 mg. *Pediatric Hypertensive Patients ≥6 years of age***:** the recommended dose is 25 mg once daily in patients>20 to <50 kg. In patients>50 kg, the usual dose is 50 mg once daily. Losartan is not recommended in pediatric patients <6 years of age or in pediatric patients with glomerular filtration rate <30 mL/min/1.73 m^2 & in children with hepatic impairment. *Hypertensive type 2 diabetic patients with proteinuria ≥ 0.5 g/day*: The usual starting dose is 50 mg once daily. *Use in patients with intravascular volume depletion:* A starting dose of 25 mg once daily should be considered. *Use in Elderly:* Although consideration should be given to initiating therapy with 25 mg in patients over 75 years of age. **CONTRINDICATIONS:** In patients who are hypersensitive to any component of this product. Do not co-administer aliskiren with Losartan in patients with diabetes. **WARNINGS & PRECAUTIONS:** Fetal Toxicity (include skull hypoplasia, anuria, hypotension, renal failure, and death), Hypotension, Hypersensitivity: Angioedema, Impaired Impaired Hepatic Function: A lower dose should be considered for patients with impaired liver function. Impaired Renal Function, Electrolyte Imbalance, Pregnancy: Female patients of childbearing age should be told about the consequences of exposure to Losartan during pregnancy. Patient receiving Losartan should be told not to use potassium supplements or salt substitutes containing potassium without consulting the prescribing physician. **DRUG INTERACTION:** Rifampin, Fluconazole, potassium-sparing diuretics (e.g., spironolactone, triamterene, amiloride), potassium supplements, or salt substitutes containing potassium, lithium, NSAIDs, Dual blockade of the RAS with angiotensin receptor blockers, ACE inhibitors, or aliskiren. **ADVERSE REACTIONS:** Asthenia/fatigue, edema/swelling, abdominal pain, chest pain, nausea, headache, pharyngitis, diarrhea, dyspepsia, myalgia, insomnia, cough, sinus disorder, fever, orthostatic effects, syncope, angina pectoris, second degree av block, cva, hypotension, myocardial infarction, arrhythmias including atrial fibrillation, palpitation, sinus bradycardia, tachycardia, ventricular fibrillation, anorexia, constipation, dental pain, dry mouth, flatulence, gastritis, vomiting, anemia, gout, arm pain, hip pain, joint swelling, knee pain, musculoskeletal pain, shoulder pain, stiffness, arthralgia, arthritis, fibromyalgia, muscle weakness, anxiety, ataxia, confusion, depression, dream abnormality, hypesthesia, decreased libido, memory impairment, migraine, nervousness, paresthesia, peripheral neuropathy, panic disorder, sleep disorder, somnolence, tremor, vertigo, dyspnea, bronchitis, pharyngeal discomfort, epistaxis, rhinitis, respiratory congestion, alopecia, dermatitis, dry skin, ecchymosis, erythema, flushing, photosensitivity, pruritus, rash, sweating, urticarial, blurred vision, burning/stinging in the eye, conjunctivitis, taste perversion, tinnitus, decrease in visual acuity, impotence, nocturia, urinary frequency, urinary tract infection, malaise, hyperkalemia, hyponatremia and rhabdomyolysis.

MARKETED BY:

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(Additional information is available on request)