ESAM LT

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

Abbreviated Prescribing information for ESAM LT (Losartan Potassium 50 mg and S-Amlodipine Besylate 2.5mg Tablets) [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: *Losartan:* Losartan Potassium is the first of a new class of antihypertensives. It is an angiotensin II receptor (Type AT1) antagonist. *S-Amlodipine:* It is a long-acting calcium channel blocker that inhibits the transmembrane influx of calcium ions into vascular smooth muscle and cardiac muscle.

INDICATION: In the treatment of mild to moderate hypertension.

DOSAGE AND ADMINISTRATION: The recommended dose is one tablet once daily taken with or without food.

CONTRINDICATIONS: In patients allergic to angiotensin receptor blocker or dihydropyridine calcium channel blocker. History of angioedema or any other adverse effect related to previous treatment with an angiotensin receptor blocker or calcium channel blocker. Do not co-administer aliskiren with Losartan in patients with diabetes.

WARNINGS & PRECAUTIONS: Fetal Toxicity: It can act on the renin-angiotensin system during the second and third trimesters of pregnancy reduces renal function and increases fetal and neonatal morbidity and death. Caution required for Hypotension — Volume-Depleted Patients, Hypersensitivity, Impaired Hepatic Function, Impaired Renal Function, Electrolyte Imbalance and Potassium Supplements.

DRUG INTERACTIONS: *Losartan:* Rifampin, an inducer of drug metabolism, decreased the concentrations of losartan and its active metabolite. Fluconazole, an inhibitor of P450 2C9, decreased active metabolite concentration and increased losartan concentration. Potassium-sparing diuretics (e.g., spironolactone, triamterene, amiloride), potassium supplements, or salt substitutes containing potassium: May lead to increases in serum potassium. Can interact with Lithium, NSAIDs, including selective COX-2 inhibitors, aliskiren, angiotensin receptor blockers and ACE inhibitors.

ADVERSE REACTIONS: Asthenia/fatigue, edema/swelling, abdominal pain, chest pain, nausea, headache, pharyngitis, diarrhea, dyspepsia, myalgia, insomnia, cough, sinus disorder, angioedema, 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, gout, arm pain, hip pain, joint swelling, knee pain, musculoskeletal pain, shoulder pain, stiffness, arthralgia, arthritis, fibromyalgia, muscle weakness, anxiety disorder, 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 and Malaise, elevations of liver enzymes and/or serum bilirubin. Edema, fatigue, flushing, dizziness,

nausea, abdominal pain, somnolence, muscle cramps, frequency of micturition or nocturia, coughing, breathlessness, epistaxis, impotence, nervousness and conjunctivitis.

MARKETED BY:

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(Additional information is available on request)