LISTRIL SM
For the use of a Registered Medical Practitioner or a Hospital or Laboratory only Abbreviated Prescribing information for Listril SM (S-Amlodipine 2.5 mg and Lisinopril 5mg tablets) [Please refer the complete prescribing information available at www.torrentpharma.com]
PHARMACOLOGICAL PROPERTIES: Lisinopril: Lisinopril is a peptidyl dipeptidase inhibitor. It inhibits the angiotensin-converting enzyme (ACE) that catalyses the conversion of angiotensin I to the vasoconstrictor peptide, angiotensin II $\boldsymbol{S}$-Amlodipine: S-Amlodipine 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 patients with mild to moderate hypertension. DOSAGE AND ADMINISTRATION: Lisinopril: Hypertension Initial Therapy: The recommended initial dose is 10 mg once a day. The usual dosage range is 20 to 40 mg per day administered in a single daily dose. Diuretic Treated Patients: If the diuretic cannot be discontinued, an initial dose of 5 mg should be used under medical supervision for at least two hours and until blood pressure has stabilized for at least an additional hour. Dosage Adjustment in Renal Impairment: The usual dose of Lisinopril (10 mg ) is recommended for patients with creatinine clearance $>30 \mathrm{~mL} / \mathrm{min}$ (serum creatinine of up to approximately $3 \mathrm{mg} / \mathrm{dL}$ ). Pediatric Hypertensive Patients $\geq 6$ years of age: The usual recommended starting dose is $0.07 \mathrm{mg} / \mathrm{kg}$ once daily (up to 5 mg total). $S$-Amlodipine: The recommended dose is 2.5 mg once daily taken with or without food, which may be increased to a maximum dose of 5 mg depending on the individual patient's response. CONTRINDICATIONS: Hypersensitive to this product and in patients with a history of angioedema. S-Amlodipine is contraindicated in patients allergic to dihydropyridine calcium antagonist. Do not co-administer aliskiren with Lisinopril in patients with diabetes. WARNINGS \& PRECAUTIONS: Lisinopril: Anaphylactoid and possibly related reactions, head and neck angioedema, intestinal angioedema, anaphylactoid reactions during desensitization, anaphylactoid reactions during membrane exposure, hypotension, leukopenia/neutropenia/agranulocytosis, hepatic failure, fetal toxicity, general aortic stenosis/hypertrophic cardiomyopathy, impaired renal function, hyperkalemia, cough, surgery/anesthesia, angioedema, symptomatic hypotension, hypoglycemia and pregnancy. $\boldsymbol{S}$ Amlodipine: Hypotension, Amlodpine is not a beta-blocker and therefore gives no protection against the dangers of abrupt beta-blocker withdrawal, Use in patients with Heart Failure, amlodipine's half-life is prolonged in patients with impaired liver function so should be administered with caution in these patients. DRUG INTERACTIONS: Lisinopril: diuretics, potassium-sparing diuretics (spironolactone, amiloride, triamterene, and others), antidiabetics (insulins, oral hypoglycemic agents), NSAIDs including selective cox-2 inhibitors, other renin-angiotensin system (RAS) blockers, lithium and gold. $\boldsymbol{S}$-Amlodipine: CYP3A4 Inhibitors (e.g., ketoconazole, itraconazole, ritonavir), grapefruit juice. ADVERSE REACTIONS: Decreases in haemoglobin, decreases in haematocrit, bone marrow depression, anaemia, thrombocytopenia, leucopenia, neutropenia, agranulocytosis, haemolytic anaemia, lymphadenopathy, autoimmune disease, hypoglycaemia, dizziness, headache, mood alterations, paraesthesia, vertigo, taste disturbance, sleep disturbances, hallucination, mental confusion, olfactory disturbance frequency, depressive symptoms, syncope, orthostatic effects, cough, rhinitis, diarrhoea, vomiting, nausea, abdominal pain and indigestion, renal dysfunction, fatigue, asthenia, increases in blood urea, increases in serum creatinine, increases in liver enzymes and hyperkalaemia.

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IN/ LISTRIL SM 5, 2.5mg /Oct-2015/01/AbPI
(Additional information is available on request)

