

VALZAAR SM

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

Abbreviated Prescribing information for VALZAAR SM [Valsartan 80mg and S-Amlodipine Besylate 2.5mg capsules] [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: *Valsartan:* Valsartan is nonpeptide and specific angiotensin II receptor blocker acting on the AT₁ receptor subtype. It blocks the vasoconstrictor and aldosterone-secreting effects of angiotensin II by selectively blocking the binding of angiotensin II to the AT₁ receptor in many tissues, such as vascular smooth muscle and the adrenal gland. *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:** Valzaar SM is indicated for the treatment of hypertension. **DOSAGE AND ADMINISTRATION:** The recommended dose is one capsule once a day. **CONTRAINDICATION:** Do not use in patients with known hypersensitivity to any component. **WARNINGS & PRECAUTIONS:** *Valsartan:* Fetal toxicity - when pregnancy is detected, discontinue product as soon as possible. Drugs that act directly on the renin-angiotensin system can cause injury and death to the developing fetus. Caution should be observed when initiating therapy in patients with heart failure or postmyocardial infarction patients for hypotension, impaired in renal function and hyperkalemia. *S-Amlodipine:* Caution required in hepatic failure patients and renal failure patients. **DRUG INTERACTIONS:** *Valsartan:* Coadministration of inhibitors of the uptake transporter (rifampin, cyclosporine) or efflux transporter (ritonavir) may increase the systemic exposure to valsartan. Concomitant use of valsartan with other agents that block the RAS, potassium sparing diuretics (e.g. spironolactone, triamterene, amiloride), potassium supplements, or salt substitutes containing potassium may lead to increases in serum potassium and in heart failure patients to increases in serum creatinine. Do not coadminister aliskiren with Valsartan in patients with diabetes. Avoid use of aliskiren with Valsartan in patients with renal impairment (GFR <60 mL/min). Monitor serum lithium levels during concomitant use with valsartan. **ADVERSE REACTIONS:** *Valsartan:* Headache, dizziness, viral infection, fatigue, abdominal pain, upper respiratory tract infection, cough, diarrhoea, rhinitis, sinusitis, nausea, pharyngitis, edema, arthralgia, elevations in creatinine level, elevated liver enzymes, increases serum potassium level and neutropenia. *S-Amlodipine:* 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)