

VALZAAR

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

Abbreviated Prescribing information for **Valzaar** [Valsartan I.P 40/80/160mg tablets] [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Valsartan is an orally active, potent, and specific angiotensin II (Ang II) receptor antagonist. It acts selectively on the AT1 receptor subtype, which is responsible for the known actions of angiotensin II. The increased plasma levels of Ang II following AT1 receptor blockade with valsartan may stimulate the unblocked AT2 receptor, which appears to counterbalance the effect of the AT1 receptor.

INDICATION: Indicated for treatment of mild to moderate hypertension and heart failure.

DOSAGE AND ADMINISTRATION: Hypertension: starting dose of Valzaar (valsartan) is 80 mg or 160 mg once daily, dose may be increased to a maximum of 320 mg. Valzaar may be administered with other antihypertensive agents and may be administered with or without food. **Heart Failure:** Starting dose of valsartan is 40 mg twice daily, maximum daily dose administered in clinical trials is 320 mg in divided doses. **Pediatric Hypertension 6-16 years of age:** For valsartan tablets, the initial dose is 40 mg once daily for children weighing below 35 kg and 80 mg once daily for those weighing 35 kg or more. The dose should be adjusted based on blood pressure response and tolerability.

CONTRAINDICATION: Hypersensitivity to the active substance or to any of the excipients. Severe hepatic impairment, biliary cirrhosis and cholestasis. Second and third trimester of pregnancy. The concomitant use of Valsartan with aliskiren-containing products is contraindicated in patients with diabetes mellitus or renal impairment (GFR < 60 ml/min/1.73 m²).

WARNINGS & PRECAUTIONS: Caution should be observed when initiating therapy in patients with hyperkalemia, impaired in renal function, Hepatic impairment, sodium-depleted and/or volume-depleted patients, Renal artery stenosis and Kidney transplantation. 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.

DRUG INTERACTIONS: Lithium, Potassium-sparing diuretics, potassium supplements, Non-steroidal anti-inflammatory medicines (NSAIDs), including selective COX-2 inhibitors, cimetidine, warfarin, furosemide, digoxin, atenolol, indomethacin, hydrochlorothiazide, amlodipine, glibenclamide.

ADVERSE REACTIONS: Decrease in hemoglobin, Decrease in haematocrit, Neutropenia, Thrombocytopenia, Hypersensitivity including serum sickness, Increase of serum potassium, hyponatremia, Vertigo, Vasculitis, Cough Abdominal pain, Elevation of liver function values including increase of serum bilirubin, Angioedema, Rash, Pruritus, Myalgia, Renal failure and impairment, Elevation of serum creatinine, Fatigue.

MARKETED BY:



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IN/VALZAAR 40, 80,160mg /APR-22/05/PI
(Additional information is available on request)