VALZAAR-H

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

Abbreviated Prescribing information VALZAAR-H (Valsartan and Hydrochlorothiazide Tablets)

[Please refer the complete prescribing information available at <u>www.torrentpharma.com</u>]

PHARMACOLOGICAL PROPERTIES: Valsartan belongs to a class of medicines known as "angiotensin II receptor antagonists", which help to control high blood pressure. Angiotensin II is a substance in the body that causes vessels to tighten, thus causing your blood pressure to increase. Valsartan works by blocking the effect of angiotensin II. As a result, blood vessels relax and blood pressure is lowered. Hydrochlorothiazide belongs to a group of medicines called thiazide diuretics (also known as "water tablets"). Hydrochlorothiazide increases urine output, which also lowers blood pressure.

DOSAGE AND ADMINISTRATION:

The recommended dose of Valzaar H is one film-coated tablet once daily or as directed by the Physician

CONTRAINDICATION:

- Hypersensitivity to active substances, other sulfonamide-derived medicinal products or to any of the excipients.
- Second and third trimester of pregnancy.
- Severe hepatic impairment, biliary cirrhosis and cholestasis.
- Severe renal impairment (creatinine clearance < 30 ml/min), anuria.
- Refractory hypokalaemia, hyponatraemia, hypercalcaemia, and symptomatic hyperuricemia.

WARNINGS & PRECAUTIONS: Concomitant use with potassium supplements, potassiumsparing diuretics, salt substitutes containing potassium, or other agents that may increase potassium levels (heparin, etc.) is not recommended. Monitoring of potassium should be undertaken as appropriate. Treatment with thiazide diuretics, including hydrochlorothiazide, has been associated with hyponatraemia and hypochloraemic alkalosis. Thiazides, including hydrochlorothiazide, increase the urinary excretion of magnesium, which may result in hypomagnesaemia. Calcium excretion is decreased by thiazide diuretics. This may result in hypercalcaemia.

DRUG INTERACTION: Concomitant use not recommended: Lithium, Concomitant use requiring caution, Pressor amines (e.g. noradrenaline, adrenaline, Non-steroidal anti-inflammatory medicines (NSAIDs), including selective COX-2 inhibitors, acetylsalicylic acid (>3 g/day), and non-selective NSAIDs. Interactions related to valsartan: Dual blockade of the Renin-Angiotensin-Aldosterone System (RAAS) with ARBs, ACEIs, or aliskiren, Concomitant use not recommended, Interactions related to hydrochlorothiazide, Calcium salts and vitamin D, Antidiabetic agents (oral agents and insulin), Beta blockers and diazoxide.

ADVERSE REACTIONS: Dehydration, Dizziness, Paraesthesia, Syncope, Vision blurred, Tinnitus, Hypotension, Cough, Non cardiogenic pulmonary oedema, Diarrhoea, Myalgia, Arthralgia, Impaired renal function, Fatigue, Serum uric acid increased, Serum bilirubin and Serum creatinine increased, Hypokalaemia, Hyponatraemia, Elevation of Blood Urea Nitrogen, Neutropenia.



IN/VALZAAR H 12.5,80,160mg /MAR-21/05/ ABPI (Additional information is available on request)