Front

Co-Valstar™

(Valsartan + Hydrochlorothiazide)

160/25 mg
tablet

کو-ویل سٹار

COMPOSITION:
Each film coated tablet contains:
Valsartan USP ..... 160 mg.
Hydrochlorothiazide USP ..... 25 mg.

Product Specs.: CCL Pharmaceuticals)

DESCRIPTION:
Co-Valstar is a combination of valsartan, an orally active, specific angiotensin II receptor blocker and hydrochlorothiazide, a diuretic.
Pharmacokinetics:
Valsartan peak plasma concentration is reached 2 to 4 hours after dosing. It has average elimination half-life of about 6 hours. Food decreases the bioavailability of valsartan. The estimated absolute bioavailability of hydrochlorothiazide after oral administration is about 70%. Peak plasma hydrochlorothiazide concentrations (C_{max}) are reached within 2 to 5 hours after oral administration. There is no clinically significant effect of food on the bioavailability of hydrochlorothiazide. Valsartan is highly bound to serum proteins (95%), mainly serum albumin. Hydrochlorothiazide is not metabolized. Valsartan is primarily recovered in feces (about 83% of dose) and urine (about 13% of dose). The recovery is mainly as unchanged drug, with only about 20% of dose recovered as metabolites. Hydrochlorothiazide: About 70% of an orally administered dose of hydrochlorothiazide is eliminated in the urine as unchanged drug.

INDICATION:
Hypertension:
Co-Valstar is the combination tablet of valsartan, an angiotensin II receptor blocker (ARB) and hydrochlorothiazide (HCTZ), a diuretic. **Co-Valstar** is indicated for the treatment of hypertension, to lower blood.
Pressure:
In patients not adequately controlled with monotherapy. As initial therapy in patients likely to need multiple drugs to achieve their blood pressure goals. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions.
Heart Failure:
Co-Valstar is indicated for the treatment of heart failure (NYHA class II-IV) in patients who are intolerant of angiotensin converting enzyme inhibitors. In a controlled clinical trial, Valsartan significantly reduced hospitalizations for heart failure.
General Considerations:
The usual starting dose is **Co-Valstar** 160/12.5 mg once daily or 80/12.5 mg once daily. The dosage can be increased after 1 to 2 weeks of therapy to a maximum of 1 tablet 160/12.5 mg twice daily as needed to control blood pressure. Maximum antihypertensive effects are attained within 2 to 4 weeks after a change in dose.
Add-on therapy:
A patient whose blood pressure is not adequately controlled with valsartan (or another ARB) alone or hydrochlorothiazide alone may be switched to combination therapy with **Co-Valstar**. A patient who experiences dose-limiting adverse reactions on either component alone may be switched to **Co-Valsatr** containing a lower dose of that component in combination with the other to achieve similar blood pressure reductions. The clinical response to **Co-Valstar** should be subsequently evaluated and if blood pressure remains uncontrolled after 3 to 4 weeks of therapy, the dose may be titrated up to a maximum of 320/25 mg.
Replacement therapy: **Co-Valstar** may be substituted for the titrated components.
Initial therapy: **Co-Valstar** is not recommended as initial therapy in patients with intravascular volume depletion.
Use with Other Antihypertensive Drugs **Co-Valstar** may be administered with other antihypertensive agents.

CONTRAINDICATIONS:
Co-Valstar is contraindicated in patients who are hypersensitive to any component of this product. Because of the Hydrochlorothiazide content, this product is contraindicated in patients with anuria or hypersensitivity to other sulfonamide-derived drugs. Do not co-administer aliskiren with **Co-Valstar** in patients with diabetes.

WARNING & PRECAUTIONS:
Renal insufficiency:
There is no apparent correlation between renal function (measured by creatinine clearance) and exposure (measured by AUC) to Valsartan in patients with different degrees of renal impairment. Thiazide diuretics are eliminated by kidney, with a terminal half-life of 5-15 hours. In patients with impaired renal function (mean creatinine clearance of 19 mL/min), the half-life of Hydrochlorothiazide elimination was lengthened to 21 hours.
Hepatic insufficiency:
On average, patients with mild-to-moderate chronic liver disease have twice the exposure (measured by AUC values) to Valsartan of healthy volunteers (matched by age, sex and weight). In general, no dosage adjustment is needed in patients with mild-to-moderate liver disease. Care should be exercised in patients with liver disease.

Back

Concomitant therapy in patients with heart failure: In patients with heart failure, concomitant use of Valsartan, an ACE inhibitor, and a beta-blocker is not recommended. In the Valsartan Heart Failure Trial, this triple combination was associated with an unfavorable heart failure.
Pregnancy & lactation:
Due to the mechanism of action of angiotensin II antagonists, a risk for the fetus cannot be excluded. In utero exposure to ACE inhibitors given to pregnant women during the 2nd & 3rd trimesters have been reported to cause injury and death to the developing fetus. As for any drug that also acts directly on the renin-angiotensin-aldosterone system, Valsartan should not be used during pregnancy. If pregnancy is detected during therapy, Valsartan should be discontinued as soon as possible.
It is not known whether Valsartan is excreted in human milk. Valsartan was excreted in the milk of lactating rats. Thus it is not advisable to use Valsartan in lactating mothers.
Safety of the Co-Valstar has not been established in pediatric patients.

ADVERSE EFFECTS:
Adverse experiences have generally been mild and transient in nature and have only infrequently required discontinuation of therapy. The overall incidence of adverse experiences with Valsartan and Hydrochlorothiazide was comparable to placebo. Some adverse reactions such as dizziness, fatigue, pharyngitis, coughing, diarrhea etc. may be observed.

DRUG INTERACTIONS:
No clinically significant pharmacokinetic interactions were observed when Valsartan was co-administered with amlodipine, atenolol, cimetidine, digoxin, furosemide, glyburide, hydrochlorothiazide or indomethacin. When **Co-Valstar** and NSAID are used concomitantly, the patient should be observed closely to determine if the desired effect of the diuretic is obtained. Concomitant use with cyclosporine may increase the risk of hyperuremicemia and gout-type complications.

INSTRUCTIONS:
- Store below 30°C.
- Protect from heat, sunlight & moisture.
- Keep out of the reach of children.
- To be sold on the prescription of a registered medical practitioner only.

PRESENTATION:
Co-Valstar 160/25 Tablet : Pack of 2 x 7 tablets.

ہدایات:
۳۰ درجہ سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔
گرمی، دھوپ اور نمی سے بچائیں۔
بچوں کی پہنچ سے دور رکھیں۔
صرف ڈاکٹر کے نسخہ پر فروخت کریں۔

FOR FURTHER INFORMATION PLEASE CONTACT:

CCL
Manufactured by:
CCL Pharmaceuticals (Pvt.) Ltd.
62 Industrial Estate, Kot Lakhpat, Lahore, Pakistan.

1852-B
25117-0001-010-0000-0000