

Composition : Cardinal : Each film coated tablet contains Valsartan USP 80mg.

Pharmacology : Valsartan (Cardival) is a nonpeptide, orally active and specific angiotensin-II antagonist, acting on the AT1 receptor subtype. Peak plasma concentration of valsartan reaches 2 to 4 hours after dosing. AUC and Cmax values of Valsartan increase approximately linearly with increasing dose. After oral administration, valsartan is primarily recovered in feces (about 83% of dose) and urine (about 13% of dose). Valsartan is highly bound to serum proteins (95%), mainly serum albumin.

Indications : Hypertension : Cardival (valsartan) is indicated for the treatment of hypertension. It may be used alone or in combination with other antihypertensive agents.

Heart Failure : Cardival (valsartan) is indicated for the treatment of heart failure (NYHA class II-IV) in patients who are intolerant of angiotensin converting enzyme inhibitors.

Dosage and administration : Hypertension: The usual dose of Valsartan is 80 mg to 160 mg once daily. Maximum dose may be 320 mg or a diuretic may be added.

Heart Failure: The usual starting dose is 40 mg twice daily and may be increased to 80 mg and 160 mg twice daily to the highest dose.

Post-Myocardial Infarction: The usual dose is 20 mg twice daily and may be increased within 7 days to 40 mg twice daily, with subsequent a target maintenance dose of 160 mg twice daily. Or, as directed by the registered physician.

Valsartan may be administered with other antihypertensive agents.

Valsartan may be administered with or without food.

Contraindication : Valsartan is contraindicated in patients with severe hepatic impairment, cirrhosis, or biliary obstruction and also contraindicated for the patient with known hypersensitivity to any component of this product.

CARDIVAL

Tablet



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Precautions : In patients with heart failure, concomitant use of Valsartan and ACE inhibitor, a Beta blocker is not recommended.

Side effects : Side-effects are as follows : dizziness, cough, headache, edema, diarrhea, nausea,, sinusitis, etc. may be observed.

Use in pregnancy and lactation : The use of valsartan is not advised at the time of pregnancy. Decision should be made whether to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

Use in Child : For children who can swallow tablets, the usual recommended starting dose is 1.3 mg/kg once daily (up to 40 mg total). The dosage should be adjusted according to blood pressure response. Valsartan is not recommended for treatment of children below the age of 6 years or children of any age with a glomerular filtration rate <30 mL/min/1.73 m².

Drug Interactions : No clinically significant pharmacokinetics interactions were observed when valsartan was co-administered with Amlodipine, Atenolol, Cimetidine, Digoxin, Furosemide, Glyburide, Hydrochlorothiazide, or Indomethacin.

Overdose : The most likely manifestations would be hypotension and tachycardia; bradycardia could occur from parasympathetic stimulation.

Storage : Store below 30°C in a dry place.

Packing : Cardinal : Each box contains 3 x 10's tablets in blister pack.