Valcap®

Capsule

Description

Valcap contains Valsartan which is a nonpeptide, orally active, and specific angiotensin II antagonist acting on the AT1 receptor subtype. Valsartan is chemically described as N-(1-oxopentyl)-N-[[2'-(1*H*-tetrazol-5-yl)[1,1'-biphenyl]-4-yl]methyl]-L-valine.

Indications

For the treatment of hypertension. It may be used alone or in combination with other antihypertensive agents.

Dosage and Administration

The recommended dose of Valcap is 80 mg once daily, irrespective of race, age, or gender. The antihypertensive effect is substantially present within 2 weeks and maximal effects are seen after 4 weeks. In patients whose blood pressure is not adequately controlled, the daily dose may be increased to 160 mg or 320 mg or a diuretic may be added. Addition of a diuretic has a greater effect than dose increases beyond 80 mg.

No dosage adjustment is required for patients with renal impairment or for patients with hepatic insufficiency of non-biliary origin and without cholestasis. Valcap may also be administered with other antihypertensive agents. The safety and efficacy of Valcap have not been established in children.

Contraindication

Hypersensivity to Valsartan or any of the components of the product.

Drug Interactions

No drug interactions of clinical significance have been found. Compounds which have been studied in clinical trials include Cimetidine, Warfarin, Furosemide, Digoxin, Atenolol, Indomethacin, Hydrochlorothiazide, Amlodipine and Glibenclamide.

As Valcap is not metabolized to a significant extent, clinically relevant drug-drug interactions in the form of metabolic induction or inhibition

of the cytochrome P450 system are not expected with Valsartan. Although valsartan is highly bound to plasma proteins, *in vitro* studies have not shown any interaction at this level with a range of molecules which are also highly protein bound, such as Diclofenac, Furosemide, and Warfarin. Concomitant use of potassium sparing diuretics (e.g., Spironolactone, Triamterene, Amiloride) potassium supplements, or salt substitutes containing potassium may lead to increase in serum potassium. If co-medication is considered necessary, caution is advisable.

Side Effects

The overall incidence of adverse experiences with Valsartan was similar to placebo. The common side effects are headache, dizziness, rhinitis, sinusitis, pharyngitis, nausea, gastrointestinal upset, oedema and fatigue. Dose related orthostatic effects were seen in less than 1% of patients. An increase in the incidence of dizziness was observed in patients treated with Valsartan 320 mg compared to 80-160 mg.

Use in Special Populations

Pregnancy : Due to the mechanisms of action of angiotensin II antagonists, a risk for the foetus cannot be excluded. In utero exposure to angiotensin converting enzyme (ACE) inhibitors given to pregnant women during the 2nd and 3rd trimesters has been reported to cause foetal injury, including hypotension, neonatal skull hypoplasia, anuria, reversible or irreversible renal failure, and death. When pregnancy is detected, Valcap should be discontinued as soon as possible.

Lactation : 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 Valcap in lactating mothers.

Pediatric use : Safety and effectiveness in paediatric patients have not been established.

Geriatric use : No overall difference in the efficacy or safety of Valsartan was observed in this patient population, but greater sensitivity of some elderly persons cannot be ruled out.

Commercial Packs

Valcap® 80 Capsule : Box containing 30 capsules in 3 x 10's blister strips. Each capsule contains Valsartan INN 80 mg.

Valcap® 160 Capsule : Box containing 20 capsules in 2 x 10's blister strips. Each capsule contains Valsartan INN 160 mg.