Valdipin®

Amlodipine Besylate BP & Valsartan USP

Composition
Valdipin®-80: Each tablet contains Amlodipine 5mg & Valsartan 80mg

Valdipin®-160: Each tablet contains Amlodipine 5mg & Valsartan 160mg

Indication
Hypertension, Angina & Heart failure

Dose
The usual starting dose is amlodipine 5mg+valsartan 80mg once daily. However, the dose may be increased to amlodipine 5mg+valsartan 160mg once daily based on condition of the patient.

Mode of action
Amlodipine inhibits the transmembrane influx of calcium ions into vascular smooth muscle and cardiac muscle. Valsartan selectively block Angiotensin Receptor Type 1 (AT1) receptor and thereby prevents the binding of Angitensin II to AT1 receptor. Blockade of AT1 receptors directly causes vasodilatation and reduces production and secretion of aldosterone–the combined effect of which is reduction of blood pressure.

Pharmacokinetic of Amlodipine
After oral administration of therapeutic doses of amlodipine, absorption produces peak plasma concentrations between 6 and 12 hours. The bioavailability of amlodipine is not altered by the presence of food. Approximately 92-95% of the circulating drug is bound to plasma proteins in hypertensive patients with an apparent volume of distribution of 21L/Kg. Steady-state plasma levels of amlodipine are reached after 7 to 8 days of consecutive daily dosing. Amlodipine is extensively metabolized in the liver with about 5% of the drug excreted in the urine. 5% of the parent compound and 62% of the metabolites are excreted in the urine with remainder eliminated via GIT. Plasma half-life of amlodipine ranges from 30 hour to 60 hour.

Pharmacokinetic of Valsartan
Peak plasma concentration of valsartan is reached 2 to 4 hours after dosing with an average elimination half-life of about 6 hours. Absolute bioavailability for valsartan is about 25% (range 10%-35%). With the tablet, food decreases the exposure (as measured by AUC) to valsartan by about 40% and peak plasma concentration (Cmax) by about 50%. AUC and Cmax values of valsartan increase approximately linearly with increasing dose over the clinical dosing range. Valsartan does not accumulate appreciably in plasma following repeated administration. Valsartan 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. Valsartan does not distribute into tissues extensively. Valsartan is highly bound to serum proteins (95%), mainly serum albumin.

Side effects
Generally, this product is well tolerated. However, few side effects including abdominal pain, swelling, back pain, dizziness, rash and cough may occur in rare cases.

Drug interaction
As with other drugs that block angiotensin II or its effects, concomitant use of potassium-sparing diuretics (e.g., spironolactone, triamterene, amiloride), potassium supplements, or salt substitutes containing potassium may lead to increases in serum potassium. The antihypertensive effect of Valsartan may be attenuated by the non-steroidal anti-inflamatory drug indomethacin.

Use in high risk group
Nursing mother: It is not known whether valsartan is excreted in human milk, but valsartan was excreted in the milk of lactating rats. Thiazides appear in human milk. Because of the potential for adverse effects on the nursing infant, a decision should be made whether to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use: Safety and effectiveness in pediatric patients have not been established.

Geriatric Use: No overall difference in the efficacy or safety of valsartan-hydrochlorothiazide was observed between geriatric patients and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

For diabetic patients: Hydrochlorothiazide may raise blood sugar levels. Check with doctor if any changes in blood sugar levels occur.

Contraindication
Valsartan is contraindicated in patients who are hypersensitive to any component of this product and who are hypersensitive to sulfonamide-derived drugs. Pregnant women should not use the drug.

Storage
Store in a cool and dry place, away from direct light and children.

Presentation
Valdipin®-80 : Each box contains 3x10 tablets in blister pack.
Valdipin®-160 : Each box contains 3x10 tablets in blister pack.

Manufactured by
RENATA LIMITED
Mirpur, Dhaka, Bangladesh
®TRADE MARK
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