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Valam®

(Amlodipine + Valsartan)
Tablet

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COMPOSITION:
Valam 5/80 Tablet:
Each film coated tablet contains:
Amlodipine Besilate BP equivalent to
Amlodipine ..... 5 mg.
Valsartan USP ..... 80 mg.

Product Specs.: CCL Pharmaceuticals

Valam 5/160 Tablet:
Each film coated tablet contains:
Amlodipine Besilate BP equivalent to
Amlodipine ..... 5 mg.
Valsartan USP ..... 160 mg.

Product Specs.: CCL Pharmaceuticals

Valam 10/160 Tablet:
Each film coated tablet contains:
Amlodipine Besilate BP equivalent to
Amlodipine ..... 10 mg.
Valsartan USP ..... 160 mg.

Product Specs.: CCL Pharmaceuticals

DRUG CLASS AND MECHANISM:
Amlodipine and Valsartan is a combination of two drugs used for treating high blood pressure (hypertension), Amlodipine and Valsartan.
Amlodipine belongs to a class of drugs called calcium channel blockers. These medications block the transport of calcium into the smooth muscle cells lining the coronary arteries and other arteries of the body. Since calcium is important in promoting contraction of muscles, blocking calcium transport relaxes the muscles that surround arteries, dilating (enlarging) the arteries of the body including the arteries of the heart (coronary arteries). Dilating arteries lowers blood pressure. Valsartan is an oral drug that belongs to a class of drugs called angiotensin receptor blockers (ARBs). Angiotensin, formed in the blood by the action of angiotensin converting enzyme (ACE) on a chemical in blood called angiotensinogen. Angiotensin is a powerful chemical that attaches to angiotensin receptors found in many tissues but primarily on smooth muscle cells surrounding blood vessels. Angiotensin's attachment to the receptors causes the blood vessels to narrow (constrict) which leads to an increase in blood pressure (hypertension). Valsartan blocks the angiotensin receptor. By blocking the action of angiotensin, Valsartan dilates blood vessels and reduces blood pressure.
Pharmacokinetics:
Amlodipine:
Peak plasma concentrations of Amlodipine are reached 6-12 hours after administration of Amlodipine alone. Absolute bioavailability has been estimated to be between 64% and 90%. The bioavailability of Amlodipine is not altered by the presence of food. Amlodipine is extensively (about 90%) converted to inactive metabolites via hepatic metabolism with 10% of the parent compound and 60% of the metabolites excreted in the urine. Elimination of Amlodipine from the plasma is biphasic with a terminal elimination half-life of about 30-50 hours. Steady state plasma levels of Amlodipine are reached after 7-8 days of consecutive daily dosing.
Valsartan:
Following oral administration of Valsartan alone peak plasma concentrations of Valsartan are reached in 2-4 hours. Absolute bioavailability is about 25% (range 10%-35%). Food decreases the exposure (as measured by AUC) to Valsartan by about 40% and peak plasma concentration (C_{max}) by about 50%. Valsartan is highly bound to serum proteins (95%), mainly serum albumin. The primary metabolite, accounting for about 9% of dose, is valeryl 4-hydroxy Valsartan. The enzyme(s) responsible for Valsartan metabolism have not been identified but do not seem to be CYP 450 isoenzymes.
Special Populations:
Geriatric:
Amlodipine: Elderly patients have decreased clearance of Amlodipine with a resulting increase in AUC of approximately 40%-60%; therefore a lower initial dose of Amlodipine may be required.
Valsartan: Exposure (measured by AUC) to Valsartan is higher by 70% and the half-life is longer by 35% in the elderly than in the young. No dosage adjustment is necessary.
Gender:
Valsartan: Pharmacokinetics of Valsartan does not differ significantly between males and females.
Renal Insufficiency:
Amlodipine: The pharmacokinetics of Amlodipine is not significantly influenced by renal impairment. Patients with renal failure may therefore receive the usual initial dose.
Valsartan: 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. Consequently, dose adjustment is not required in patients with mild-to-moderate renal dysfunction. No studies have been performed in patients with severe impairment of renal function (creatinine clearance < 10 mL/min). Valsartan is not removed from the plasma by hemodialysis. In the case of severe renal disease, exercise care with dosing of Valsartan.
Hepatic Insufficiency:
Amlodipine: Patients with hepatic insufficiency have decreased clearance of Amlodipine with resulting increase in AUC of approximately 40%-60%; therefore, a lower initial dose of Amlodipine may be required.
Valsartan: 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.

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INDICATIONS:
Valam is used for treating high blood pressure in patients not adequately controlled on one blood pressure medication or for initial therapy if it is not likely that one drug will achieve adequate control.

DOSAGE AND ADMINISTRATION:
The usual dose is 5mg/160mg to 10mg/320mg daily. The majority of the effect is seen within 2 weeks.

DRUG INTERACTIONS:
Combining Valsartan with potassium-sparing diuretics (for example, spironolactone [Aldactone], triamterene, amiloride, potassium supplements, or salt substitutes containing potassium may lead to hyperkalemia (elevated potassium in the blood), and in heart failure patients, it increases serum creatinine, a test used for monitoring function of the kidneys.

WARNING & PRECAUTIONS:
Pregnancy: When used in the second or third trimester of pregnancy Valsartan may cause injury and even death to the fetus. Valsartan should not be used during pregnancy. When pregnancy is detected, Amlodopin/Valsartan should be stopped as soon as possible.
Nursing mothers: It is not known whether Amlodopin/Valsartan is secreted into human milk. To prevent adverse effects in the infant, mothers should use alternative agents or discontinue nursing.
Paediatric use: Safety and effectiveness of Amlodipine and Valsartan in paediatric patients have not been established.
Geriatric Use: No overall difference in the efficacy or safety of Amlodipine and Valsartan was observed in patient (≥ 65years) with hypertension, but greater sensitivity of some older individuals cannot be ruled out.

CONTRAINDICATIONS:
Data is not available

SIDE EFFECTS:
Side effects include headache, dizziness, fatigue, abdominal pain, cough, diarrhea and nausea. Patients may also experience hyperkalemia, impotence, reduced renal function, and allergic reactions. Angioedema (swelling of soft tissues including those of the throat and larynx) is a rare but serious side effect of Valsartan.

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:

Valam 5/80 Tablet	:	Pack of 2 x 7 tablets.
Valam 5/160 Tablet	:	Pack of 2 x 7 tablets.
Valam 10/160 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:

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