Amlosartan®

Amlodipine & Valsartan tablet

Presentation
Amlosartan® 5/80: Each tablet contains Amlodipine Besilate BP equivalent to Amlodipine 5 mg & Valsartan USP 80 mg.
Amlosartan® 5/160: Each tablet contains Amlodipine Besilate BP equivalent to Amlodipine 5 mg & Valsartan USP 160 mg.
Amlosartan® 10/160: Each tablet contains Amlodipine Besilate BP equivalent to Amlodipine 10 mg & Valsartan USP 160 mg.

Description
Amlodipine is a dihydropyridine calcium channel blocker that inhibits the transmembrane influx of calcium ions into vascular smooth muscle and cardiac muscle. Amlodipine has a greater effect on vascular smooth muscle cells than on cardiac muscle cells. Amlodipine is a peripheral arterial vasodilator that acts directly on vascular smooth muscle to cause a reduction in peripheral vascular resistance and reduction in blood pressure.
Valsartan is an oral medication that belongs to a class of drugs called Angiotensin Receptor Blockers (ARBs). It is orally active and specific angiotensin II antagonist acting on the AT_1 subtype. Angiotensin's attachment to the receptors cause the blood vessels to narrow (vasoconstrict) which leads to an increase in blood pressure (hypertension). Valsartan blocks the angiotensin II receptor. By blocking the action of angiotensin, Valsartan dilates blood vessels and reduces blood pressure without affecting pulse rate. Valsartan has much greater affinity (about 20,000-fold) for the AT_1 receptor than for the AT_2 receptor. It does not bind or block other hormone receptors or ion channels known to be important in cardiovascular regulation.

Indication
Amlosartan is indicated for the treatment of hypertension. This combination drug is not indicated for the initial therapy of hypertension.

Dosage and administration
Amlodipine is an effective treatment of hypertension in once daily doses of 2.5 mg to 10 mg while Valsartan is effective in doses of 80 mg to 320 mg. The majority of the antihypertensive effect is attained within 2 weeks after initiation of therapy or a change in dose. The dosage can be increased after 1 to 2 weeks of therapy to a maximum of one 10/320 mg tablet once daily as needed to control blood pressure.
Amlosartan may be administered with or without food. Amlosartan may be administered with other antihypertensive agents. A patient whose blood pressure is not adequately controlled with Amlodipine alone or with Valsartan alone may be switched to their combination therapy.
Elderly patients: Because of decreased clearance of Amlodipine, therapy should usually be initiated at 2.5 mg.
Renal impairment: No initial dosage adjustment is required for patients with mild or moderate renal impairment. Titrate slowly in patients with severe renal impairment.
Hepatic impairment: No initial dosage adjustment is required for patients with mild or moderate liver insufficiency. Titrate slowly in patients with hepatic impairment.

Side effects
The most common side effects include peripheral edema, vertigo, nasopharyngitis, upper respiratory tract infection and dizziness.

Contraindications
Amlodipine and Valsartan combination is contraindicated in patients who are hypersensitive to any compounds of this product.

Precautions
Amlosartan should be used with caution because there is a risk for-
- Fetal or neonatal morbidity
- Hypotension
- Myocardial infarction or increased angina

Dose should be titrated slowly in patients with impaired hepatic or severely impaired renal function. In general, calcium channel blockers should be used with caution in patients with heart failure.

Drug interactions
No drug interaction studies have been conducted with this combination. Although studies have been conducted with the individual Amlodipine and Valsartan components.

Overdosage
Limited data of human overdosage have been reported.

Use in Pregnancy and Lactation
Pregnancy: Amlodipine and Valsartan combination should not be used in 2^{nd} and 3^{rd} trimester because it can cause fetal death .
Nursing Mothers: It is not known whether Valsartan and Amlodipine are excreted 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
The safety and effectiveness has not been established in pediatric patients.

Geriatric use
No differences in overall incidence of adverse events were observed in elderly.

Commercial pack
Amlosartan® 5/80: Each box contains 3 alu-alu blister strips of 10 tablets.
Amlosartan® 5/160: Each box contains 3 alu-alu blister strips of 10 tablets.
Amlosartan® 10/160: Each box contains 3 alu-alu blister strips of 10 tablets.

Manufactured by
incepta
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Dhaka, Bangladesh

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