

Calsart

(Amlodipine 5 mg + Olmesartan 20 mg)

Presentation

Calsart Tablet: Each film coated tablet contains Amlodipine Besylate BP equivalent to Amlodipine 5 mg and Olmesartan Medoxomil INN 20 mg.

Description

Calsart is a combination of two antihypertensive drugs: Olmesartan Medoxomil, an angiotensin II receptor blocker and Amlodipine Besylate is a dihydropyridine calcium channel blocker. The combination of these active ingredients has an additive antihypertensive effect, reducing blood pressure to a greater degree than either component alone. The Olmesartan medoxomil blocks the vasoconstrictor effects of angiotensin II and the Amlodipine inhibits the transmembrane influx of calcium ions into cardiac and vascular smooth muscle.

Indication

Calsart alone or with other antihypertensive agents are indicated for the treatment of hypertension. **Calsart** may also be used as initial therapy in patients who are likely needed to multiple antihypertensive agents to achieve their blood pressure goals.

Dosage & Administration

Maximum antihypertensive effects are attained within 2 weeks. **Calsart** may be taken with or without food.

Initial Therapy

The usual starting dose of **Calsart** is one tablet (5/20 mg) once daily. The dosage can be increased after 1 to 2 weeks of therapy to a maximum dose of (10/40 mg) once daily as needed to control blood pressure. Initial therapy with this combination product is not recommended in patients > 75 years old or with hepatic impairment.

Replacement Therapy

Calsart may be substituted for its individually titrated components. When substituting for individual components, the dose of one or both of the components can be increased if blood pressure control has not been satisfactory.

Add-on Therapy

Calsart may be used to provide additional blood pressure lowering effect in patients who are not adequately controlled with Amlodipine (or another dihydropyridine calcium channel blocker) alone or with Olmesartan Medoxomil (or another angiotensin II receptor blocker) alone.

Elderly patients: No dosage adjustment is necessary in elderly patient.

Children: The safety & effectiveness in pediatric patients have not been established.

Contraindication

Combination of Amlodipine and Olmesartan is contraindicated in patients who are hypersensitive to any component of this product or to any of its ingredients.

Precaution

Caution should be exercised in patients with volume or salt depletion, severe aortic stenosis, severe obstructive coronary artery disease, congestive heart failure, impaired renal function and hepatic impairment. No initial dosage adjustment is recommended for patients with moderate to marked renal impairment (creatinine clearance <40 ml/min). Combination of Amlodipine and Olmesartan is not recommended below creatinine clearance <20 ml/min.

Side effect

The most common side effect include edema, flushing, dizziness, palpitation. Other side effect include hypotension, rash, pruritus, urinary frequency and nocturia.

Use in Pregnancy and Lactation:

Pregnancy- Pregnancy Category C.

Lactation- It is not known whether the Amlodipine or Olmesartan Medoxomil is excreted in human milk.

Drug Interaction

Clinical trial indicates that Amlodipine has no effect on the human plasma protein binding of Digoxin, Phenytoin, and Warfarin. No significant drug interaction were reported when Olmesartan was co-administered with Digoxin & Warfarin.

Overdose

If massive overdose occurs, active cardiac and respiratory monitoring should be instituted. Frequent blood pressure measurements are essential and treatment should be supportive.

Storage Condition

Store in a cool and dry place. Protect from light and moisture. Keep out of reach of children.

Commercial Pack

Calsart Tab: Each box contains 3×10 tablets in Alu-Alu blister strips.

Manufactured by:



GLOBE PHARMACEUTICALS LTD.
Noakhali, Bangladesh.