

Only for the use of Medical Professionals

Abecab[®]

Amlodipine Besylate & Olmesartan Medoxomil

Description

Abecab[®] is a combination preparation of Amlodipine Besylate & Olmesartan Medoxomil. Amlodipine is a calcium channel blocker that acts directly on vascular smooth muscle to cause a reduction in peripheral vascular resistance and reduction in blood pressure. Olmesartan blocks the vasoconstrictor effects of Angiotensin II by selectively blocking the binding of Angiotensin II to the AT₁ receptor in vascular smooth muscle. Its action is, therefore, independent of the pathways for Angiotensin II synthesis.

Indications

Abecab[®] is indicated for the treatment of hypertension, alone or with other antihypertensive agents.

Abecab[®] may also be used as initial therapy in patients who are likely to need multiple antihypertensive agents to achieve their blood pressure goals.

Dosage and administration

General considerations

Maximum antihypertensive effects are attained within 2 weeks. Abecab[®] may be taken with or without food. Abecab[®] may be administered with other antihypertensive agents. Dosage may be increased after 2 weeks. The maximum recommended dose of Abecab[®] is 2 tablets (10/40 mg) once daily.

Initial therapy

The usual starting dose of Abecab[®] is one tablet (5/20 mg) once daily. Depending on the blood pressure response, the dose may be titrated at intervals of 1-2 weeks to two tablets of Abecab[®] (10/40 mg) once daily.

Replacement therapy

Abecab[®] 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

Abecab[®] may be used to provide additional blood pressure lowering for patients not adequately controlled with Amlodipine (or another dihydropyridine calcium channel blocker) alone or with Olmesartan Medoxomil (or another Angiotensin receptor blocker) alone.

Elderly patients

No dosage adjustment is necessary in elderly patients \geq 65 years age.

Patients with hepatic impairment

Initial therapy with Abecab[®] is not recommended in patient's \geq 75 years and in patients with hepatic impairment.

Children

The safety and effectiveness of Abecab[®] in pediatric patients have not been established.

Use in pregnancy and lactation

Olmesartan medoxomil: Pregnancy Categories C (first trimester) and D (second and third trimesters).

Amlodipine: There are no adequate and well-controlled studies in pregnant women. Amlodipine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

When pregnancy is detected, discontinue this Amlodipine and Olmesartan combination as soon as possible.

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

Side effects

The overall incidence of side effects on therapy with Amlodipine and Olmesartan combination was similar to that seen with corresponding doses of the individual components and to placebo. The common side effects include edema, hypotension, orthostatic hypotension, rash, pruritus, palpitation, urinary frequency, and nocturia.

Contraindications

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

Precautions

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.

Drug Interactions

In vitro data indicate that Amlodipine has no effect on the human plasma protein binding of digoxin, phenytoin, warfarin, and indomethacin. No significant drug interactions were reported when Olmesartan was co-administered with digoxin or warfarin.

Overdosage

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

Pharmaceutical precautions

Store in a cool and dry place. Protect from light.

Presentation

Abecab[®] tablet: Each coated tablet contains Amlodipine Besylate BP equivalent to 5 mg Amlodipine and Olmesartan medoxomil INN 20 mg.

Package quantities

Abecab[®] tablet: Carton of 30 tablets in Alu-PVC blister.

® Registered Trade Mark



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