Amdova®

Amlodipine + Atorvastatin

Tablet

Description

It is a combination product containing Amlodipine Besilate BP equivalent to 5 mg Amlodipine, a calcium channel blocker and Atorvastatin calcium INN equivalent to 10 mg Atorvastatin, a statin (HMG-CoA reductase inhibitor).

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.

Atorvastatin calcium is a synthetic lipid-lowering agent. It is an inhibitor of 3-hydroxy-3-methyl-glutaryl-coenzyme A (HMG-CoA). This enzyme catalyzes the conversion of HMG-CoA to mevatonate, an early and rate limiting step in the synthesis of cholesterol.

Indications

Patients in whom treatment with Amlodipin and Atorvastatin is appropriate at the dose presented, which include hypertension, chronic stable angina, an adjunct to diet for hypercholesterolemia and in hypertensive patient with multiple risk factors for CHD to reduce the risk of non fatal MI and non fatal stroke.

Amlodipine:

1. Hypertension: Amlodipine is indicated for the treatment of hypertension. It may be used alone or in combination with other antihypertensive agents; 2. Coronary Artery Disease (CAD): Chronic Stable Angina: Amlodipine is indicated for the treatment of chronic stable angina. Amlodipine may be used alone or in combination with other antianginal or antihypertensive agents; Vasospastic Angina (Prinzmetal's or Variant Angina): Amlodipine is indicated for the treatment of confirmed or suspected vasospastic angina. Amlodipine may be used as monotherapy or in combination with other antianginal drugs. Angiographically Documented CAD: In patients with recently documented CAD by angiography and without heart failure or an ejection fraction <40%, Amlodipine is indicated to reduce the risk of hospitalization due to angina and to reduce the risk of a coronary revascularization procedure.

Atorvastatin:

Atorvastatin is indicated as an adjunct to diet to reduce elevated total cholesterol, LDL- cholesterol, apolipoprotein B and triglyceride levels in patients with primary hypercholesterolemia (heterozygous familial and non familial) and mixed dyslipidemia (Fredrickson Types IIa and IIb), adjunctive therapy to diet for the treatment of patients with elevated serum triglyceride levels (Fredrickson Type IV), for the treatment of patients with primary dysbetalipoproteinemia (Fredrickson Type III) who do not respond adequately to diet, to reduce total-C and LDL-C in patients with homozygous familial hypercholesterolemia as an adjunct to other lipid lowering treatments (e.g. LDL apheresis) or if such treatments are unavailable. At the time of hospitalization for an acute coronary event, consideration can be given to initiating drug therapy at discharge if the LDL-C level is > 100 mg/dL (NCEP-ATP III). Prior to initiating therapy with Atorvastatin, secondary causes for hypercholesterolemia (e.g., poorly controlled diabetes mellitus, hypothyroidism, nephrotic syndrome, dysproteinemias, obstructive liver disease, other drug therapy, and alcoholism) should be excluded, and a lipid profile performed to measure total-C, LDL-C, HDL-C, and TG.

Dosage

Amlodipine: The usual initial antihypertensive oral dose is 5 mg once daily with a maximum dose of 10 mg once daily. Elderly individuals or patients with hepatic insufficiency may be started on 2.5 mg once daily dose and this dose may be used when adding Amlodipine to other antihypertensive therapy. Dosage should be adjusted according to each patient's need. The recommended dose for chronic stable or vasospastic angina is 5-10 mg, with the lower dose suggested in the elderly and in patients with hepatic insufficiency.

Atorvastatin: Adults: The patient should be placed on a standard cholesterol-lowering diet before receiving Atorvastatin and should continue on this diet during treatment with Atorvastatin Hypercholesterolemia (Heterozygous Familial and Nonfamilial) and Mixed Dyslipidemia (Fredrickson Types IIa and IIb): The recommended starting dose of Atorvastatin is 10 mg daily. The dosage range is 10 to 80 mg once daily. Atorvastatin can be administered as a single dose at any time of the day with or without food. Homozygous Familial Hypercholesterolemia: The dosage of Atorvastatin in patients with homozygous FH is 10 to 80 mg daily. Patients with renal insufficiency: Renal disease has no influence on the plasma concentrations or lipid effects of Atorvastatin; thus no adjustment of dose is required. Hemodialysis is not expected to significantly enhance the clearance of Atorvastatin since the drug is extensively bound to plasma proteins. Patients with hepatic dysfunction: In patients with moderate to severe hepatic dysfunction, the therapeutic response to Atorvastatin is unaffected but exposure to the drug is greatly increased.

Side Effects

Amlodipine: General: Since the vasodilatation induced by Amlodipine is gradual in onset, acute hypotension has rarely been reported after oral administration of Amlodipine. Nonetheless, caution should be exercised when administering Amlodipine as with any other peripheral vasodilator particularly in patients with severe aortic stenosis. *Use in Patients with Congestive Heart Failure:* Although hemodynamic studies and a controlled trial in Class-II-III heart failure patients have shown that Amlodipine did not lead to clinical deterioration as measured by exercise tolerance, left ventricular ejection fraction, and clinical symptoms. In general, all calcium channel blockers should be used with caution in patients with heart failure. Beta-blocker Rhabdomyolysis with acute renal failure secondary to myoglobinuria has been reported with other drugs in this class. *Atorvastatin:* Atorvastatin may cause an elevation in serum creatine phosphokinase levels. This should be considered in the differential diagnosis of chest pain in patients on therapy with Atorvastatin. Uncomplicated myalgia has been reported in Atorvastatin-treated patients. Atorvastatin therapy should be discontinued if markedly elevated CPK levels occur or myopathy is diagnosed or suspected. Side effects: Atorvastatin is generally well tolerated. Adverse effects reported commonly include constipation, flatulence, dyspepsia, abdominal pain, headache, nausea, myalgia, diarrhea, asthenia and insomnia.

Contraindications

Amlodipine: Amlodipine is contraindicated in patients with known hypersensitivity to Amlodipine. *Atorvastatin:* Contraindicated in hypersensitivity to any component of this medication. Active liver disease or unexplained persistent elevations of serum transaminases exceeding three times the upper limit of normal. *Pregnancy/Lactation:* Safety in pregnancy has not been established. Use of HMG-CoA reductase inhibitors during breast feeding is not recommended. *Pediatrics:* Safety and efficacy of Atorvastatin have not been established in children. *Geriatrics:* Efficacy and safety in older patients using recommended doses is similar to that seen in the general population.

Warning

Increased Angina and/or Myocardial Infarction Rarely, patients, particularly those with severe obstructive coronary artery disease, have developed documented increased frequency, duration and/or severity of angina or acute myocardial infarction on starting calcium channel blocker therapy or at the time of dosage increase. The mechanism of this effect has not been elucidated. Liver Dysfunction. HMG-CoA reductase inhibitors, like some other lipid-lowering therapies, have been associated with biochemical abnormalities of liver function.

Precaution

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Atorvastatin: Rhabdomyolysis with acute renal failure secondary to myoglobinuria has been reported with other drugs in this class. Atorvastatin may cause an elevation in serum creatine phosphokinase levels. This should be considered in the differential diagnosis of chest pain in patients on therapy with Atorvastatin. Uncomplicated myalgia has been reported in Atorvastatin-treated patients. Atorvastatin therapy should be discontinued if markedly elevated CPK levels occur or myopathy is diagnosed or suspected.

Pharmaceutical Precaution

Store in cool & dry place, away from children.

Commercial Pack

Amdova® Tablet: Box containing 30 tablets. Each tablet contains Amlodipine Besilate BP equivalent to 5 mg Amlodipine and Atorvastatin calcium INN equivalent to 10 mg Atorvastatin.

BEXIMCO PHARMA

Manufactured by

BEXIMCO PHARMACEUTICALS LTD.

TONGI, BANGLADESH BL 6625 241109

148mm x 210 mm FS

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