Only for the use of Medical Professionals

Arbitel AM

Amlodipine and Telmisartan

Description

Arbitel® AM is a combination of Telmisartan and Amlodipine where Telmisartan is a non-peptide angiotensin II receptor antagonist and Amlodipine is calcium channel blocker. Angiotensin II is formed from angiotensin I in a reaction catalyzed by angiotensin converting enzyme. Angiotensin II is the principal agent of the renin-angiotensin system, with effects that include vasoconstriction, stimulation of synthesis and release of aldosterone, cardiac stimulation, and renal reabsorption of sodium. Telmisartan blocks the vasoconstrictor and aldosterone secreting effects of angiotensin II by selectively blocking the binding of angiotensin II to the AT_1 receptor in many tissues, such as vascular smooth muscle and the adrenal gland. Its action is therefore independent of the pathways for angiotensin II synthesis. 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.

Indication

Arbitel® AM is indicated for the treatment of hypertension alone or with other antihypertensive agents. **Arbitel® AM** is indicated as initial therapy in patients likely to need multiple antihypertensive agents to achieve their blood pressure goals.

Dosage and administration

Treatment of hypertension

Initiate with **Arbitel® AM** 5/40 mg or 5/80 mg once daily. Dosage may be increased after at least 2 weeks to a maximum dose of 10/80 mg once daily, usually by increasing one component at a time but both components can be raised to achieve more rapid control. Majority of antihypertensive effect is attained within 2 weeks.

Pediatric use

Safety and effectiveness in pediatric patients have not been established.

Hepatic Insufficiency

Monitor carefully and titrate slowly in patients with biliary obstructive disorders or hepatic insufficiency. Since patients with hepatic impairment have decreased clearance of Amlodipine, start amlodipine or add Amlodipine 2.5 mg to Telmisartan. The lowest dose is 5/40 mg; therefore, initial therapy with Arbitel® AM tablets is not recommended in hepatically impaired patients.

Use in pregnancy & lactation

Pregnancy

Pregnancy Categories C (first trimester) and D (second and third trimesters). When pregnancy is detected or expected, Telmisartan and Amlodipine should be discontinued as soon as possible.

Lactation

Telmisartan

It is not known whether Telmisartan is excreted in human milk, but Telmisartan was shown to be present in the milk of lactating rats. Because of the potential for adverse effects on the nursing infant, decide whether to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

Amlodipine

It is not known whether Amlodipine is excreted in human milk. In the absence of this information, it is recommended to discontinue nursing while amlodipine is administered.

Side effects

The most common adverse reactions are peripheral edema, dizziness, and hypotension.

Contraindications

It is contraindicated in patients with known hypersensitivity of Telmisartan or Amlodipine or any of the excipients of the products.

Precautions

Avoid fetal or neonatal exposure. Correct any volume or salt depletion before initiating therapy. Observe for signs and symptoms of hypotension. Titrate slowly in patients with hepatic or severe renal impairment. Monitor for worsening in Heart Failure patients. Avoid concomitant use of an ACE inhibitor and angiotensin receptor blocker. Uncommonly, initiating a CCB in patients with severe obstructive coronary artery disease may precipitate myocardial infarction or increased angina.

Drug interaction

Drug Interactions with Telmisartan

When certain medicines are taken together, there is a possibility of developing drug interactions. With Telmisartan, drugs such as potassium supplements or potassium-sparing diuretics may cause an interaction. When Telmisartan was co-administered with digoxin, median increases in digoxin peak plasma concentration (49%) and in through concentration (20%) where observed. NSAID use may lead to increased risk of renal impairment and loss of antihypertensive effect. Monitor renal function periodically in patients receiving Telmisartan and NSAID therapy.

Drug Interactions with Amlodipine
In clinical trials, Amlodipine has been safely administered with thiazide diuretics, beta-blockers, angiotensin-converting enzyme inhibitors, long-acting nitrates, sublingual nitroglycerin, digoxin, warfarin, non-steroidal anti-inflammatory drugs, antibiotics, and oral hypoglycemic drugs. The following have no clinically relevant effects on the pharmacokinetics of Amlodipine: cimetidine, grapefruit juice, sildenafil. Amlodipine has no clinically relevant effects on the pharmacokinetics or pharmacodynamics of atorvastatin, digoxin, and warfarin.

Overdose
Telmisartan:
Limited data are available with regard to overdose in humans. The most likely manifestation of overdose with Telmisartan would be hypotension, dizziness and tachycardia. If overdose occur, supportive treatment should be given.

Amlodipine:
Single oral doses of Amlodipine besilate or maleate equivalent to 40 mg/kg and 100 mg/kg amlodipine in mice and rats, respectively, caused deaths. Single oral doses equivalent to 4 or more mg/kg amlodipine in dogs (11 or more times the maximum recommended human dose on a mg/m2 basis) caused a marked peripheral vasodilation and hypotension.

Pharmaceutical precautions
Store in a cool (below 25°C) and dry place. Protect from light.

Presentation

Arbitel® AM 5/40 tablet**:** Each coated tablet contains Amlodipine Besilate BP 6.935mg equivalent to 5mg Amlodipine & Telmisartan BP 40 mg.

Arbitel® AM 5/80 tablet**:** Each coated tablet contains Amlodipine Besilate BP 6.935mg equivalent to 5mg Amlodipine & Telmisartan BP 80 mg.

Package quantities
Arbitel® AM 5/40 tablet**:** Carton of 30 tablets in blister pack.

Arbitel® AM 5/80 tablet**:** Carton of 30 tablets in blister pack.

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