Presart AM

Amlodipine & Telmisartan Tablet

Presentation
Presart AM 5/40 Tablet: Each bi-layer tablet contains Amlodipine 5 mg (as Amlodipine Besilate BP) and Telmisartan USP 40 mg

Presart AM 5/80 Tablet: Each bi-layer tablet contains Amlodipine 5 mg (as Amlodipine Besilate BP) and Telmisartan USP 80 mg

Description
Presart AM is a combination of a dihydropyridine calcium antagonist, Amlodipine and an angiotensin II receptor blocker, Telmisartan. The Amlodipine component of Presart AM inhibits the transmembrane influx of calcium ions into vascular smooth muscle and cardiac muscle. 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. The Telmisartan component of Presart AM blocks the vasoconstriction effects of angiotensin II by selectively blocking the binding of angiotensin II to the AT1 receptor in vascular smooth muscle.

Indications
Presart AM is indicated for the treatment of hypertension, alone or with other antihypertensive agents. It may also be used as initial therapy in patients who are likely to need multiple drugs to achieve their blood pressure goals.

Dosage and Administration

Initial Therapy: Presart AM is indicated if multiple medications are needed to control blood pressure. The usual starting dose is Presart AM 5/40 mg once daily. Patients requiring larger blood pressure reductions may be started with Presart AM 5/80 mg once daily. Initial therapy with Presart AM is not recommended in patients ≥75 years old or with hepatic impairment.

Add-on Therapy: If Telmisartan or Amlodipine monotherapy is not sufficient to control blood pressure, Presart AM is indicated. Patients treated with 10 mg Amlodipine who experience adverse reactions such as edema, may be switched to Presart AM 5/40 mg tablets once daily, reducing the dose of Amlodipine without reducing the overall expected antihypertensive response.

Replacement Therapy: Patients receiving Amlodipine and Telmisartan from separate tablets may instead receive Presart AM tablets containing the same component doses once daily.

Pediatric use
Safety and effectiveness of Amlodipine + Telmisartan combination in pediatric patients have not been established.

Geriatric use
Initial therapy with Amlodipine + Telmisartan combination is not recommended in patients ≥ 75 years old.

Hepatic impairment
Initial therapy with Amlodipine + Telmisartan combination is not recommended in hepatically impaired patients.

Side Effects
Dizziness, peripheral edema, migraine, headache, paraesthesia, vertigo, bradycardia, palpitations, hypotension, cough, abdominal pain, diarrhea, nausea, pruritus, myalgia, spasm, erectile dysfunction, chest pain, fatigue, edema etc.

Precautions

- Avoid fetal or neonatal exposure
- Hypotension: 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
- Heart failure: Monitor for worsening
- Avoid concomitant use of an ACE inhibitor and angiotensin receptor blocker
- Myocardial infarction: Uncommonly, initiating a CCB in patients with severe obstructive coronary artery disease may precipitate myocardial infarction or increased angina

Contraindications
Known hypersensitivity to this product or any of its components. Pregnancy & lactation. Biliary obstructive disorders, severe hepatic impairment, hypotension, cardiogenic shock, left ventricle outflow tract obstruction.

Overdose

Amlodipine: Over dosage might be expected to cause excessive peripheral vasodilation with marked hypotension and possibly reflex tachycardia. If massive overdose occur, active cardiac and respiratory monitoring should be instituted.

Telmisartan: Limited data are available with regard to over dosage in humans. The most likely manifestations of over dosage with Telmisartan tablets would be hypotension, dizziness, and tachycardia; bradycardia could occur from parasympathetic (vagal) stimulation.

Drug Interactions
Co-administration of Telmisartan did not result in a clinically significant interaction with Acetaminophen, Amlodipine, glyburide, simvastatin, hydrochlorothiazide, warfarin, or ibuprofen. Telmisartan is not metabolized by the cytochrome P450 system and had no effects in vitro on cytochrome P450 enzymes, except for some inhibition of CYP2C19.

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 the following: atorvastatin, digoxin, warfarin.

Use in Pregnancy & Lactation
Pregnancy: Amlodipine & Telmisartan combinations should not be used during pregnancy. Pregnancy Categories C (first trimester) and D (second and third trimesters).

Lactation: It is not known whether Amlodipine and Telmisartan is excreted in human milk. Because of the potential for adverse effects on the nursing infant, discontinue nursing or discontinue the drug after taking into account the importance of the drug to the mother.

Storage
Store below 30°C and dry place, away from light. Keep out of the reach of children.

Packing
Presart AM 5/40 Tablet: Each box contains 3 blister packs with each blister of 10 tablets.

Presart AM 5/80 Tablet: Each box contains 3 blister packs with each blister of 10 tablets.

Manufactured by:
general GENERAL Pharmaceuticals Ltd.
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