

Olmepres ^{AM}

Olmesartan Medoxomil 20 mg &
Amlodipine 5 mg Tablet

Presentation

Each film coated tablet contains Olmesartan Medoxomil BP 20 mg & Amlodipine 5 mg (as Amlodipine Besilate BP).

Description

Olmepres AM is a combination of a dihydropyridine calcium antagonist, Amlodipine and an angiotensin II receptor blocker, Olmesartan Medoxomil. The Amlodipine component of **Olmepres 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 Olmesartan Medoxomil component of **Olmepres 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

Olmepres AM is indicated for the treatment of hypertension, alone or with other antihypertensive agents. **Olmepres AM** may also be used as initial therapy in patients who are likely to need multiple antihypertensive agents to achieve their blood pressure goals. The decision to use a combination as initial therapy should be individualized and should be shaped by considerations such as baseline blood pressure, the target goal, and the incremental likelihood of achieving goal with a combination compared to mono therapy. Individual blood pressure goals may vary based upon the patient's risk.

Dosage & Administration

Initial Therapy:

The usual starting dose of **Olmepres AM** is 20/5 mg once daily. The dosage can be increased after 1 to 2 weeks of therapy to a maximum dose of two tablet of **Olmepres AM** (20/5 mg) once daily as needed to control blood pressures. Maximum antihypertensive effects are attained within 2 weeks after a change in dose. **Olmepres AM** may be taken with or without food. **Olmepres AM** may be administered with other antihypertensive agents. Initial therapy with **Olmepres AM** is not recommended in patients ≥ 75 years old or with hepatic impairment.

Replacement Therapy:

Substitute individually titrated components for patients on Amlodipine & Olmesartan Medoxomil. This combination may also be given with increased amounts of Amlodipine, Olmesartan Medoxomil, or both, as needed.

Add-on Therapy:

Olmepres AM may be used to provide additional blood pressure lowering for patients not adequately controlled with amlodipine (or another calcium channel blocker) alone or with Olmesartan Medoxomil (or another angiotensin receptor blocker) alone.

Geriatric Use

No overall differences in safety or effectiveness were observed between subjects 65 years of age or older and younger subjects.

Pediatric Use

The safety and effectiveness of **Olmepres AM** in pediatric patients have not been established.

Side Effects

Dizziness, Edema, Flushing and Headache

Contraindications

Olmepres AM can't be co-administered with Aliskiren in patients with diabetes.

Precautions

Amlodipine & Olmesartan Medoxomil combination should be used with caution in-

1. Hypotension in Volume- or Salt-Depleted Patients
2. Vasodilation in patients with severe aortic stenosis
3. Patients with Severe Obstructive Coronary Artery Disease
4. Patients with Congestive Heart Failure
5. Patients with Impaired Renal Function
6. Patients with Hepatic Impairment

Use in Pregnancy and Lactation

Pregnancy Category D

Pregnancy: Amlodipine and Olmesartan Medoxomil combination should not be used in second and third trimesters of pregnancy because it can cause fetal death. When pregnancy is detected, discontinue this combination as soon as possible.

Nursing Mother: It is not known whether the Amlodipine or Olmesartan Medoxomil components of **Olmepres AM** are excreted in human milk, but Olmesartan is secreted at low concentration in the milk of lactating rats. Because of the potential for adverse effects on the nursing infant, a decision should be made whether to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

Drug Interactions

The antihypertensive effect of angiotensin II receptor antagonists, including Olmesartan Medoxomil may be attenuated by NSAIDs including selective COX-2 inhibitors. Blood pressure, renal function & electrolytes should be closely monitored in patients on combination therapy & other agents that affect the RAAS.

Over Dosage

There is no information on over dosage with this combination in humans

Storage Conditions

Store in a cool & dry place, away from light. Keep out of the reach of children.

Commercial Pack

Each box contains 3 blister packs of 10 tablets.

Manufactured by:

 **GENERAL**
Pharmaceuticals Ltd.
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