Olpres A

Olmesartan Medoxomil BP and Amlodipine Besilate BP

Composition
Olpres A 20/5 Tablet: Each film coated tablet contains Olmesartan Medoxomil BP 20 mg and Amlodipine Besilate BP equivalent to Amlodipine 5 mg.
Olpres A 40/5 Tablet: Each film coated tablet contains Olmesartan Medoxomil BP 40 mg and Amlodipine Besilate BP equivalent to Amlodipine 5 mg.

Description
Olpres A is a combination product containing Amlodipine, a calcium channel blocker and Olmesartan, an angiotensin II receptor blocker. Amlodipine is a dihydropyridine calcium channel blocker that inhibits the transmembrane influx of calcium ions into vascular smooth muscle & cardiac muscle.
Amlodipine is a peripheral arterial vasodilator that acts directly on vascular smooth muscle to cause a reduction in peripheral vascular resistance & a reduction in blood pressure. Olmesartan is an angiotensin II receptor blocker that acts on AT1 subtype. By blocking the action of angiotensin II, Olmesartan dilates blood vessels and reduces blood pressure without affecting pulse rate.

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

Dosage and Administration
Initial Therapy: The usual starting dose of **Olpres A** is 20/5 mg once daily. The dosage can be increased after 1 to 2 weeks of therapy to a maximum of 40/10 mg tablet once daily to control blood pressure. Initial therapy with **Olpres A** is not recommended in patients ≥ 75 years old or with hepatic impairment.

General Considerations
The side effects of Olmesartan medoxomil are generally and apparently independent of dose. Those of Amlodipine are generally dose-dependent (mostly edema). Maximum antihypertensive effects are attained within 2 weeks after a change in dose. **Olpres A** may be taken with or without food. **Olpres A** may be administered with other antihypertensive agents. Dosage may be increased after 2 weeks up to maximum recommended dose of 40/10 mg.
Replacement Therapy: **Olpres A** 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: **Olpres A** may be used to provide additional blood pressure lowering for patients not adequately controlled with amlodipine (or another dihyropyridine calcium channel blocker) alone or with Olmesartan medoxomil (or another angiotensin receptor blocker) alone.

Contraindication
Hypersensitivity to Olmesartan Medoxomil or Amlodipine. Do not co-administer aliskirin with **Olpres-A** in patients with diabetes.

Adverse Reaction
The most common side effects include peripheral edema, flushing, palpitations, dizziness. Other adverse reactions that occurred in placebo-controlled clinical trials are orthostatic hypotension, diarrhea, rash, abdominal pain, fatigue, back pain, pruritus, rhabdomyolysis.

Warning & Precautions
• Fetal/Neonatal Morbidity and Mortality: When pregnancy is detected, this combination should be discontinued as soon as possible.
• Hypotension in Volume or salt-Depleted Patients: Symptomatic hypotension may occur after initiation of treatment.
• Vasodilatation: Caution should be exercised when administering the drug, particularly in patients with severe aortic stenosis.
• Patients with Severe Obstructive Coronary Artery Disease: Patients may develop increased frequency, duration, or severity of angina or acute myocardial infarction on starting calcium channel blocker therapy or at the time of dosage increase.
• Patients with Congestive Heart Failure: Calcium channel blockers should be used with caution in patients with heart Failure.
• Patients with Impaired Renal Function: Caution should be exercised when administering the drug to patients with renal impairment.
• Patients with Hepatic Impairment: Caution should be exercised when administering the drug to patients with severe hepatic impairment.

Pregnant women
When pregnancy is detected, discontinue **Olpres A** as soon as possible. When used in pregnancy during the second and third trimesters, drugs that act directly on the renin-angiotensin system can cause injury and even death to the developing fetus.
Nursing Mothers: Because of the potential for adverse effects on the nursing infant, a decision should be made whether to discontinue nursing or discontinue the drug.

Pediatric Use
The safety and effectiveness of Amlodipine & Olmesartan combination in pediatric patients have not been established.

Geriatric patients
Dose selection for an elderly patient should be cautions, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function and of concomitant disease or other drug therapy.

Drug Interaction
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. No significant drug interactions were reported in studies in which Olmesartan Medoxomil was co-administered with digoxin or warfarin, antacids. Olmesartan Medoxomil is not metabolized by the cytochrome P-450 system and has no effects on P-450 enzymes.

Storage
Do not store above 25^0 C. Protect from light. Keep out of reach of children.

Packaging
Olpres A 20/5 Tablet: Each box contains 3×10's tablets in blister pack.
Olpres A 40/5 Tablet: Each box contains 3×10's tablets in blister pack

P-3050

Manufactured by
ZISKA PHARMA
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Kaliakoir, Gazipur, Bangladesh

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