Orbapin

Tablet

Amlodipine and Olmesartan Medoxomil

Description
Orbapin is a combination of two antihypertensive drugs containing Amlodipine, a dihydropyridine calcium channel blocker and Olmesartan Medoxomil, an angiotensin II receptor antagonist. Amlodipine inhibits the transmembrane influx of calcium ions into vascular smooth & cardiac muscle. Amlodipine is a peripheral arterial vasodilator that acts directly on vascular smooth muscle to cause a reduction in peripheral vascular resistance and a reduction in blood pressure. Olmesartan is an angiotensin II receptor antagonist that acts on AT_1 subtype by blocking the action of angiotensin II receptor. Olmesartan dilates blood vessels and reduces blood pressure without affecting pulse rate.

Composition
Orbapin 5/20: Each film-coated tablet contains Amlodipine Besilate BP equivalent to Amlodipine 5 mg and Olmesartan Medoxomil BP 20 mg.

Orbapin 5/40: Each film-coated tablet contains Amlodipine Besilate BP equivalent to Amlodipine 5 mg and Olmesartan Medoxomil BP 40 mg.

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

Dosage & Administration
Initial therapy
The usual starting dose of Orbapin is one tablet (5/20 mg) once daily. The starting dosage can be increased after 1 to 2 weeks of therapy to a maximum dose of two tablets of Orbapin (5/20 mg) once daily as needed to control blood pressure. Orbapin5/40 may be administered in patients whose blood pressure is not adequately controlled by Orbapin 5/20. Maximum antihypertensive effects are attained within 2 weeks after a change in dose. Orbapin may be taken with or without food. Orbapin may be administered with other antihypertensive agents. Initial therapy with this combination is not recommended in patient's ≥75 years old or with hepatic impairment. No initial dose adjustment is recommended for patients with moderate to marked renal impairment (Creatinine clearance < 40 mL/min). Combination of Amlodipine and Olmesartan is not recommended below Creatinine clearance < 20 mL/min.
Replacement therapy
Orbapin may be substituted for its individual 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
Orbapin may be used to provide additional blood pressure lowering for patients not adequately control with Amlodipine (or another dihydropyridine calcium channel blocker) alone or with Olmesartan Medoxomil (or another angiotensin II receptor blocker) alone.
OR, AS DIRECTED BY PHYSICIAN.

Side Effects
The reported side effects were generally mild and seldom led to discontinuation of treatment. The most common side effects include peripherial edema, flushing, palpitations, dizziness. Other side effects that occurred in placebo-controlled clinical trials are orthostatic hypotension, diarrhea, rash, abdominal pain, fatigue, back pain, pruritus, rhabdomyolysis.

Contraindication
Hypersensitivity to any of the component of this combination product.

Precautions
Hypotension in Volume or Salt-Depleted patients: Symptomatic hypotension may occur initiation of treatment. Vasodilation: Cautions 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. Patient 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.

Use in pregnancy & Lactation
Pregnancy: When pregnancy is detected, discontinue this combination product 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.
Lactation: Because of the potential for adverse effects on the nursing infant, a decision should be made whether to discontinue nursing or discontinue the drug.

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

Drug Interactions
In clinical trials, Amlodipine has been safely administered with thiazide diuretic, beta blockers, angiotensin converting enzyme inhibitors, long acting nitrates, sublingual nitroglycerin, digoxin, warfarin, NSAID's, antibiotic and oral hypoglycemic drugs. No significant drug interactions were reported in studies in which Olmesartan Medoximil was co-administered with digoxin or warfarin, antacids. Olmesartan Medoxomil is not metabolized by the cytochrome P450 system and has no effects on P450 enzymes.

Over dose
There is no information on over dose with Amlodipine and Olmesartan Medoxomil in human.

Supply
ORBAPIN 5/20 : Each box contains 3x10 tablets in Alu-Alu blister strips.
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Keep all medicines out of reach of children.
Store in a cool & dry place, protected from light.

* Further information is available on request.

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Manufactured by:
The ACME Laboratories Ltd.
Dhamrai, Dhaka, Bangladesh
For Health, Vigour and Happiness