

Bizoran 20

Indications

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

Therapeutic Class

Combined antihypertensive preparations

Pharmacology

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.

Dosage & Administration

Initial Therapy: The usual starting dose of Amlodipine & Olmesartan is one tablet (5/20 mg) once daily. The dosage can be increased after 1 to 2 weeks of therapy to a maximum dose is two tablets (10/40 mg) once daily as needed to control blood pressure. This may be taken with or without food and may be administered with other antihypertensive agents. Initial therapy with this combination product is not recommended in patients ≥ 75 years old or with hepatic impairment.

Replacement Therapy: Amlodipine & Olmesartan 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: Amlodipine & Olmesartan may be used to provide additional blood pressure lowering for patients not adequately controlled with Amlodipine (or another dihydropyridine calcium channel blocker) alone or with Olmesartan Medoxomil (or another angiotensin II receptor blocker) alone.

Interaction

The pharmacokinetics of Amlodipine and Olmesartan Medoxomil are not altered when the drugs are co-administered. No drug interaction studies have been conducted with Amlodipine and Olmesartan combination tablet and other drugs, although studies have been conducted with the individual Amlodipine and Olmesartan Medoxomil components and no significant drug interactions have been observed.

Contraindications

Hypersensitivity to any of the component of this combination product.

Side Effects

The reported adverse reactions were generally mild and seldom led to discontinuation of treatment. The most common side effects include edema, dizziness, flushing, palpitation. Other side effects may include vomiting, diarrhoea, rhabdomyolysis, alopecia, pruritus, urticaria etc.

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.

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, taking into account the importance of the drug to the mother.

Precautions & Warnings

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.

Use in Special Populations

The safety and effectiveness in pediatric patients have not been established.

Overdose Effects

There is no experience of overdose with Amlodipine & Olmesartan combination. The most likely effects of olmesartan medoxomil overdosage are hypotension and tachycardia; bradycardia could be encountered if parasympathetic (vagal) stimulation occurred.

Amlodipine overdosage can be expected to lead to excessive peripheral vasodilatation with marked hypotension and possibly a reflex tachycardia. Marked and potentially prolonged systemic hypotension up to and including shock with fatal outcome has been reported.

Storage Conditions

Keep out of the reach of children. Store below 30°C. Keep in the original package in a cool & dry place in order to protect from light and moisture.