Olvance-AM

Olmesartan Medoxomil + Amlodipine

COMPOSITION

Olvance AM 20/5 mg Tablet: Each film coated tablet contains Olmesartan Medoxomil BP 20 mg and Amlodipine Besilate BP equivalent to Amlodipine 5 mg.

PHARMACOLOGY

This product is a combination of two antihypertensive drugs: Olmesartan Medoxomil is an Angiotensin-II receptor blocker and Amlodipine is a dihydropyridine calcium antagonist. The Olmesartan Medoxomil component blocks the vasoconstrictor effects of angiotensin-II and The Amlodipine component inhibits the transmembrane influx of calcium ions into vascular smooth muscle.

INDICATION

Olvance AM is indicated for the treatment of hypertension, alone or with other antihypertensive agents. Olvance AM may also be taken 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 recommended dosage of Olvance AM is one tablet once daily.

Olvance AM 20/5 tablet may be administered in patients whose blood pressure is not adequately controlled by 20 mg Olmesartan Medoxomil or 5 mg Amlodipine alone.

The dosage can be increased after 1 to 2 weeks of therapy to a maximum dose of 40/10 mg once daily as needed to control blood pressure. Olvance AM may be taken with or without food. Olvance AM my 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

Olvance AM 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.

Route of Administration

Oral route only.

CONTRAINDICATION

Aliskiren is contraindicated with Olvance AM in patients with diabetes.

PRECAUTION AND WARNING

When pregnancy is detected, this combination drug should be discontinued as soon as possible. Symptomatic hypotension may occur after initiation of therapy. Olvance AM should be used with caution in patients with congestive heart failure, impaired renal function / hepatic impairment, patients with severe aortic stenosis, severe obstructive coronary artery disease. Patients may develop increased frequency, duration or severity of angina or acute MI or starting Calcium Channel Blocker therapy or at the time of dosage increase. As with other angiotensin receptor antagonists and ACE inhibitors, hyperkalaemia may occur during treatment with Olmesartan medoxomil, especially in the presence of renal impairment and/or heart failure. Olmesartan medoxomil inhibits the renin-angiotensin system (RAS) and drugs that inhibit the RAS can cause hyperkalaemia. Monitor serum electrolytes periodically. Close monitoring of serum potassium levels is recommended.

SIDE EFFECTS

Common

The most common side effect include peripheral oedema, dizziness, flushing, vomiting, diarrhoea, rhabdomyolysis, alopecia, pruritus, urticaria etc.

Rare

Face oedema, Hypersensivity, syncope, urticaria etc.

USE IN PREGNANCY AND 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 Mother

Because of the potential for adverse effects on the rusing 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.

USE IN CHILDREN & ADOLESCENTS

Olvance AM is recommended for use in children & adolescents below 18 years of age due to lack of data on safety & efficacy.

DRUG INTERACTION

With medicine

Based on experience with the use of other drugs that affect the renin-angiotensin system, concomitant use of potassium-sparing diuretics, potassium supplements, salt substitutes containing potassium levels (e.g. heparin) may lead to increases in serum potassium. Such concomitant use is therefore not recommended.

With food & others

Administration of amlodipine with grapefruit or grapefruit juice is not recommended as bioavailability may be increased in some patients resulting in increased blood pressure lowering effects.

OVERDOSE

Symptoms

There is no experience of overdose with Olvance AM. The most likely effects of Olmesartan medoxomil overdose 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.

Treatment

If intakes is recent, gastric lavage or induction of emesis may be considered. In healthy subjects, the administration of activated charcoal immediately or up to 2 hours after ingestion of amlodipine has been shown to reduce substantially the absorption of amlodipine. Clinically significant hypotension due to an overdose of Olvance AM requires active support of the cardiovascular system, including close monitoring of heart and lung function, elevation of the extremities, and attention to circulating fluid volume and urine output. A vasoconstrictor may be helpful in restoring vascular tone and blood pressure, provided that there is no contraindication to its use. Intravenous calcium gluconate may be beneficial in reversing the effects of calcium channel blockade. Since amlodipine is highly protein-bound, dialysis is not likely to be of benefit. The dialysability of Olmesartan medoxomil is unknown.

STORAGE

Store in cool & dry place below 30^{O}C, Protect form light & moisture.

Keep out of the reach of children.

COMMERCIAL PACK

Olvance AM 20/5 mg tablet: Each box containing 3X10 box in Alu-Alu Blister pack.

Manufactured by

BIOPHARMA
LIMITED
A-116, BSCIC Industrial Estate
TONGI, GAZIPUR, BANGLADESH

For further query on the use of this medicine, consult to a registered Doctor or Pharmacist.