Olmetor® AM

Amlodipine BP + Olmesartan Medoxomil USP

COMPOSITION

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

Olmetor® AM 5/40 tablet : Each film coated tablet contains Amlodipine Besilate BP equivalent to Amlodipine 5 mg and Olmesartan Medoxomil USP 40 mg.

PHARMACOLOGY

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

INDICATION

Olmetor® AM is indicated for the treatment of hypertension, alone or with other antihypertensive agents. **Olmetor® AM** 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 recommended dosage of **Olmetor® AM** is one tablet once daily. **Olmetor® AM** 5/20 tablet may be administered in patients whose blood pressure is not adequately controlled by 20 mg Olmesartan Medoxomil or 5 mg Amlodipine alone. **Olmetor® AM** 5/40 may be administered in patients whose blood pressure is not adequately controlled by **Olmetor® AM** 5/20 tablet. The dosage can be increased after 1 to 2 weeks of therapy to a maximum dose of 10/40 mg once daily as needed to control blood pressure. **Olmetor® AM** may be taken with or without food. **Olmetor® AM** 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

Olmetor® 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 **Olmetor® 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. **Olmetor® 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 on 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 effects 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 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.

USE IN CHILDREN & ADOLESCENTS

Olmetor® AM is not 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 or other drugs that may increase serum 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 **Olmetor® AM** 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.

Treatment

If intake 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 **Olmetor® 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 dialy sability of olmesartan is unknown.

STORAGE

Store in cool and dry place below 30°C, protect from light & moisture. Keep out of reach of children.

COMMERCIAL PACK

Olmetor® AM 5/20 tablet: Each box contains 3 x10's tablet in Alu-Alu blister pack.

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EURO

Manufactured by

EURO Pharma Ltd.

In Pursuit of Excellence

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