OLMETOR AM

For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory

Abbreviated Prescribing information for OLMETOR AM (Olmesartan Medoxomil 20/40mg and Amlodipine Besilate 5mg Tablets)[Please refer the complete prescribing information available at www.torrentpharma.com

PHARMACOLOGICAL PROPERTIES: Olmetor AM provided as a tablet for oral administration, is a combination of the calcium channel blocker (CCB) amlodipine besylate and the angiotensin II receptor blocker (ARB) olmesartan medoxomil.

INDICATION: For the treatment of mild to moderate hypertension.

DOSAGE AND ADMINISTRATION: The usual starting dose of Olmetor AM is 5/20 mg once daily. The dosage can be increased after 1 to 2 weeks of therapy to a maximum dose of one 10/40 mg tablet once daily as needed to control blood pressure.

CONTRAINDICATION: Do not co-administer aliskiren with Olmetor AM in patients with diabetes.

WARNINGS & PRECAUTIONS: Use of drugs that act on the renin-angiotensin system during the second and third trimesters of pregnancy reduces fetal renal function and increases fetal and neonatal morbidity and death. Resulting oligohydramnios can be associated with fetal lung hypoplasia and skeletal deformations. Potential neonatal adverse effects include skull hypoplasia, anuria, hypotension, renal failure, and death. When pregnancy is detected, discontinue combination of Amlodipine and Olmesartan as soon as possible. Symptomatic hypotension may be anticipated after initiation of treatment with olmesartan medoxomil. Patients with severe obstructive coronary artery disease, may develop increased frequency, duration, or severity of angina or acute myocardial infarction, hepatic enzyme elevations, increased blood creatinine levels and hyperkalemia have been reported.

DRUG INTERACTIONS: NSAIDS, colesevelam hydrochloride and Lithium.

ADVERSE REACTIONS: Asthenia, dizziness, flushing, palpitation, somnolence, angioedema, anaphylactic reactions, peripheral edema, vomiting, diarrhea, sprue-like enteropathy, rhabdomyolysis, acute renal failure, alopecia, pruritus, urticaria, gynecomastia, jaundice and hepatic enzyme elevations.

MARKETED BY:

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(Additional information is available on request)