OLMETOR CH

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

Abbreviated Prescribing information for OLMETOR CH (Olmesartan Medoxomil 20,40mg and Chlorthalidone 12.5mg tablets)[Please refer the complete prescribing information available at www.torrentpharma.com

PHARMACOLOGICAL PROPERTIES: - Olmesartan blocks the vasoconstrictor effects of angiotensin II by selectively blocking the binding of angiotensin II to the AT1 receptor in vascular smooth muscle. Chlorthalidone produces diuresis with increased excretion of sodium and chloride.

INDICATION: For the treatment of hypertension, to lower blood pressure in patients not adequately controlled with monotherapy and as an initial therapy in patients likely to need multiple drugs to help achieve blood pressure goals.

DOSAGE AND ADMINISTRATION: The usual initial dosage is one tablet of Olmetor CH 20mg orally once daily. A patient whose blood pressure is not adequately controlled, the dose may be increased, if necessary according to physician's discretion to two tablets of Olmetor CH 20 or one tablet of Olmetor CH 40 once a day.

CONTRAINDICATION: In patients with known hypersensitivity or any other component of this product. Because of the chlorthalidone component, this product is contraindicated in patients with anuria or hypersensitivity to other sulfonamide-derived drugs. 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 and hyperuricemia have been reported. Severe, chronic diarrhea with substantial weight loss has been reported in patients taking olmesartan months to years after drug initiation.

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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IN/OLMETOR CH 20,40,12.5mg/Oct-2015/01/AbPI

(Additional information is available on request)