OLMETOR

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

Abbreviated Prescribing information for OLMETOR (Olmesartan Medoxomil 20,40mg 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.

INDICATION: For the treatment of mild to moderate hypertension

DOSAGE AND ADMINISTRATION: The usual recommended starting dose of Olmesartan is 20 mg once daily when used as monotherapy in patients who are not volume-contracted. For patients requiring further reduction in blood pressure after 2 weeks of therapy, the dose of Olmesartan may be increased to 40 mg. For **Pediatric Hypertension** (6 to 16 years of age) dosage must be individualized. For children who can swallow tablets, the usual recommended starting dose of Olmesartan is 10 mg once daily for patients who weigh 20 to <35 kg (44 to 77 lb), or 20 mg once daily for patients who weigh ≥35 kg.

CONTRAINDICATION: Do not co-administer aliskiren with Olmesartan in patients with diabetes **WARNINGS & PRECAUTIONS: Fetal toxicity** 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. **Morbidity in Infants children** <1 year of age must not receive Olmesartan for hypertension. Drugs that act directly on the renin-angiotensin aldosterone system (RAAS) can have effects on the development of immature kidneys. In patients with an activated reninangiotensin aldosterone system, such as volume- and/or salt-depleted patients (e.g., those being treated with high doses of diuretics), symptomatic hypotension may be anticipated after initiation of treatment with Olmesartan. Impaired Renal Function, Sprue-like Enteropathy 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: Chest pain, peripheral edema, vertigo, abdominal pain, dyspepsia, gastroenteritis, nausea, tachycardia, hypercholesterolemia, hyperlipemia, hyperuricemia, elevations of liver enzymes and/or serum bilirubin were observed infrequently, adult hypertension, asthenia, dizziness, flushing, palpitation, somnolence, angioedema, anaphylactic reactions, peripheral edema, vomiting, diarrhea, , rhabdomyolysis, alopecia, pruritus, urticaria, gynecomastia, jaundice and hepatic enzyme elevations.

MARKETED BY:



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(Additional information is available on request)