OLMETOR M

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

Abbreviated Prescribing information for OLMETOR M (**Olmesartan Medoxomil 20mg and Metoprolol Succinate 25/50 mg(ER) 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 AT_1 receptor in vascular smooth muscle. Metoprolol a b-blocker is anti hypertensive and used to treat heart failure. **INDICATION:** For the treatment of essential hypertension **DOSAGE AND ADMINISTRATION:** It is once daily preparation tablets to be swallowed whole, not to be crushed, chewed or broken. **Adult hypertension** -the therapy should be started with low dose. The dose may be increased based on clinical response of the patients on weekly basis up to two unit of olmesartan medoxomil 20mg with metoprolol succinate 50mg once daily**. Pediatric Hypertensive Patients** ≥ 6 Years of age: Olmesartan medoxomil: maximum of 20 mg once daily for patients who weigh <35 kg or 40 mg once daily for patients who weigh ≥35 kg. **Metoprolol:** maximum initial dose should not exceed 50 mg once daily. Then dose can be titrated up to two unit of olmesartan medoxomil 20mg with metoprolol succinate 50mg once daily. For patients with possible depletion of intravascular volume (e.g., patients treated with diuretics, particularly those with impaired renal function), initiate Olmesartan under close medical supervision and give consideration to use of a lower starting dose. **CONTRAINDICATION:** Do not co-administer aliskiren with Olmesartan in patients with diabetes. Contraindicated in severe bradycardia, second or third degree heart block, cardiogenic shock, decompensated cardiac failure, sick sinus syndrome, and in patients who are hypersensitive to any component of this product. **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 c**hildren <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 renin-angiotensin 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**. **Metoprolol-** Ischemic heart disease, heart failure, bronchospastic disease, pheochromocytoma, diabetes and hypoglycemia, hepatic impairment, thyrotoxicosis, anaphylactic reaction and peripheral vascular disease.**DRUG INTERACTIONS:** NSAIDS, colesevelam hydrochloride and Lithium. **Metoprolol -**catecholamine depleting drugs, CYP2D6 inhibitors, digitalis, clonidine, and calcium channel blockers. **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. **Metoprolol -** Cold extremities, arterial insufficiency (usually of the Raynaud type), palpitations, peripheral edema, syncope, chest pain and hypotension, wheezing, dyspnea, confusion, short-term memory loss, headache, somnolence, nightmares, insomnia, anxiety/nervousness, hallucinations, paresthesia, nausea, dry mouth, constipation, flatulence, heartburn, hepatitis, vomiting, musculoskeletal pain, arthralgia, blurred vision, decreased libido, male impotence, tinnitus, reversible alopecia, agranulocytosis, dry eyes, worsening of psoriasis, Peyronie's disease, sweating, photosensitivity, taste disturbance, reversible mental depression progressing to catatonia, an acute reversible syndrome characterized by disorientation for time and place, short-term memory loss, emotional lability, clouded sensorium, and decreased performance on neuropsychometrics, agranulocytosis, nonthrombocytopenic/ thrombocytopenic purpura, laryngospasm,

respiratory distress, elevated levels of serum transaminase, alkaline phosphatase, and lactate dehydrogenase.

MARKETED BY:

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