TRI-OLMETOR

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

Abbreviated Prescribing information for TRI-OLMETOR (Olmesartan Medoxomil 20/40mg, Amlodipine Besilate 5mg and Hydrochlorothiazide 12.5mg Tablets) [Please refer the complete prescribing information available at www.torrentpharma.com

PHARMACOLOGICAL PROPERTIES: Fixed dose combination of olmesartan medoxomil, amlodipine and hydrochlorothiazide is a combination of an angiotensin II receptor antagonist, olmesartan medoxomil, a calcium channel blocker, amlodipine besilate and a thiazide diuretic, hydrochlorothiazide. The combination of these ingredients has an additive antihypertensive effect, reducing blood pressure to a greater degree than each component alone.

INDICATION: Treatment of essential hypertension. This fixed combination drug is not indicated for the initial therapy of hypertension **DOSAGE AND ADMINISTRATION:** Dosage may be increased after 2 weeks. The full blood pressure lowering effects are attained within 2 weeks after a change in dose. It may be taken with or without food. **CONTRAINDICATION:** Do not co-administer aliskiren with Olmesartan in patients with diabetes. Hypersensitivity to the active substances, to dihydropyridine derivates or to sulfonamide-derived substances (since hydrochlorothiazide is a sulfonamide-derived drug) or to any of the excipients, severe renal impairment or anuria, refractory hypokalaemia, hypercalcaemia, hyponatraemia and symptomatic hyperuricaemia, severe hepatic insufficiency, cholestasis and biliary obstructive disorders, 2nd and 3rd trimester of pregnancy. Due to the amlodipine component, fixed dose combination of olmesartan medoxomil, amlodipine and hydrochlorothiazide is contraindicated in patients with: Shock (including cardiogenic shock), severe hypotension ,obstruction of the outflow tract of the left ventricle (e.g. high grade aortic stenosis), haemodynamically unstable heart failure after acute myocardial infarction. **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. sprue-like enteropathy**, Amlodipine-**vasodilation, **Hydrochlorothiazide** hypersensitivity reaction, systemic lupus erythematosus, lithium interaction, acute myopia and secondary angle-closure glaucoma. **DRUG INTERACTIONS:** NSAIDS, colesevelam hydrochloride and lithium. **amlodipine-**cimetidine, grapefruit juice, antacid, sildenafil, **hydrochlorothiazide-** alcohol, barbiturates, or narcotics, antidiabetic drugs (oral agents and insulin) – dosage adjustment of the antidiabetic drug may be required, cholestyramine and colestipol resins, corticosteroids, – intensified electrolyte depletion, particularly hypokalemia., pressor amines (e.g. norepinephrine) – possible decreased response to pressor amines but not sufficient to preclude their use. skeletal muscle relaxants, non depolarizing (e.g. tubocurarine) – possible increased responsiveness to the muscle relaxant. **ADVERSE REACTIONS:** Upper respiratory tract infection, nasopharygitis, urinart tract infection, leucopenis, thrombocytopenia, hypokalemia, glycosuria, hypercalcemia, hypermagnesemia, confusional state, visual disturbances, cough, bronchitis, dyspnoea, constipation, muscle spasm, myalgia, blood creatinine and uric acid increased, 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:

TORRENT PHARMACEUTICALS LTD.
Torrent House, Off Ashram Road,
Ahmedabad-380 009, INDIA

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(Additional information is available on request)