

## TRI-OLMETOR

**For the use of a Registered Medical Practitioner or Hospital or a Laboratory only.**  
Abbreviated Prescribing information TRI-OLMETOR (Olmesartan Medoxomil, Amlodipine  
& Hydrochlorothiazide Tablets)

[Please refer the complete prescribing information available at [www.torrentpharma.com](http://www.torrentpharma.com)]

### PHARMACOLOGICAL PROPERTIES:

**Mechanism of action:** TRI-OLMETOR 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.

**DOSAGE AND ADMINISTRATION:** The tablet should be swallowed with a sufficient amount of fluid (e. g. one glass of water). The tablet should not be chewed and should be taken at the same time each day. TRI-OLMETOR can be taken with or without food.

### CONTRAINDICATION:

Hypersensitivity to the active substances, to dihydropyridine derivatives or to sulfonamide-derived substances (since hydrochlorothiazide is a sulfonamide-derived drug) or to any of the excipients listed. Severe renal impairment, Refractory hypokalaemia, hypercalcaemia, hyponatraemia and symptomatic hyperuricaemia, Severe hepatic insufficiency, cholestasis and biliary obstructive disorders, 2nd and 3rd trimester of pregnancy, the concomitant use of TRI-OLMETOR with aliskiren-containing products is contraindicated in patients with diabetes mellitus or renal impairment (GFR < 60 mL/min/1.73 m<sup>2</sup>). Due to the amlodipine component, TRI-OLMETOR 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:** Patients with hypovolaemia or sodium depletion, Other conditions with stimulation of the renin-angiotensin-aldosterone system, Renovascular hypertension, Renal impairment and kidney transplantation, Dual blockade of the renin-angiotensin-aldosterone system (RAAS), Hepatic impairment, Aortic and mitral valve stenosis, obstructive hypertrophic cardiomyopathy, Primary aldosteronism, Metabolic and endocrine effects, Electrolyte imbalance, Lithium, Heart failure, Sprue-like enteropathy, Choroidal Effusion, Acute Myopia and Secondary Angle-Closure Glaucoma, Pregnancy, Paediatric population, Elderly, Photosensitivity, Non-melanoma skin cancer

### DRUG INTERACTION:

**Potential interactions related to the TRI-OLMETOR combination: Concomitant use not recommended:** Lithium **Concomitant use requiring caution:** Baclofen, Non-steroidal anti-inflammatory medicinal products **Concomitant use to be taken into account:** Amifostine, Alcohol, barbiturates, narcotics or antidepressants

**Potential interactions related to olmesartan medoxomil: Concomitant use not recommended:** ACE-inhibitors, angiotensin II receptor blockers or aliskiren, Medicinal products affecting potassium levels

**Potential interactions related to amlodipine: Concomitant use requiring caution:** Effects of other medicinal products on amlodipine, CYP3A4 inhibitors, CYP3A4 inducers, Effects of amlodipine on other medicinal products

**Potential interactions related to hydrochlorothiazide:**

**Concomitant use not recommended:** Medicinal products affecting potassium levels

**Concomitant use requiring caution:** Calcium salts, Cholestyramine and colestipol resins, Digitalis glycosides, Medicinal products affected by serum potassium disturbances, Non-depolarizing skeletal muscle relaxants (e. g. tubocurarine), Anticholinergic agents (e. g. atropine, biperiden), Anticholinergic agents (e. g. atropine, biperiden), Antidiabetic medicinal products (oral agents and insulin): Metformin, Beta-blockers and diazoxide, Pressor amines (e. g. noradrenaline), Medicinal products used in the treatment of gout (e. g. probenecid, sulfinpyrazone and allopurinol) Amantadine, Cytotoxic agents (e. g. cyclophosphamide, methotrexate), Salicylates, Methyldopa, Cyclosporine, Tetracyclines

**ADVERSE REACTIONS: Clonazepam:** Upper respiratory tract infection, Nasopharyngitis, Urinary tract infection, Non-melanoma skin cancer (Basal cell carcinoma and Squamous cell carcinoma), Leucopenia, Thrombocytopenia, Bone marrow depression, Neutropenia/Agranulocytosis, Haemolytic anaemia, Aplastic anaemia, Anaphylactic reaction, Drug hypersensitivity, Hyperkalaemia, Hypokalaemia, Anorexia, Glycosuria, Hypercalcaemia, Hyperglycaemia, Hypomagnesaemia, Hyponatramia, Hypochloroemia, Hypertriglyceridaemia, Hypercholesterolaemia, Hypercholesterolaemia, Hypochloroemic, alkalosis, Depression, Apathy, Restlessness, Mood changes (including anxiety), Sleep disorders (including insomnia), Dizziness, Headache, Postural dizziness, Presyncope, Dysgeusia, Hypertonia, Hypoaesthesia, Paraesthesia, Peripheral neuropathy, Somnolence, Syncope, Convulsions, Loss of appetite, Tremor, Extrapyramidal disorder, Visual disturbance (including diplopia, blurred vision), Lacrimation decreased, Worsening of myopia, Xanthopsia, Acute myopia, acute angle closure, Glaucoma, Choroidal effusion, Vertigo, Palpitations, Tachycardia, Myocardial infarction, Arrhythmia (including bradycardia, ventricular tachycardia and atrial fibrillation), Angina pectoris, Hypotension, Flushing, Orthostatic hypotension, Vasculitis (including necrotising angiitis), Thrombosis, Embolism, Cough, Bronchitis, Dyspnoea, Pharyngitis, Rhinitis, Acute interstitial pneumonia, Respiratory distress, Pulmonary oedema, Nausea, Constipation, Dry mouth, Abdominal pain, Abdominal pain, Dyspepsia, Gastritis, Gastric irritation, Gingival hyperplasia, Paralytic ileus, Pancreatitis, Vomiting, Sprue-like enteropathy, Hepatitis, Jaundice (intrahepatic cholestatic icterus), Acute cholecystitis, Alopecia, Angioedema, Allergic dermatitis, Erythema multiforme, Erythema, Cutaneous lupus erythematoses-like reactions, Exanthema, Exfoliative dermatitis, Hyperhidrosis, Photosensitivity reactions, Pruritus, Purpura, Quincke oedema, Rash, Reactivation of cutaneous lupus erythematoses, Toxic epidermal necrolysis, Skin discoloration, Stevens-Johnson syndrome, Muscle spasm, Joint swelling, Muscular weakness, Ankle swelling, Arthralgia, Arthritis, Back pain, Paresia, Myalgia, Skeletal pain, Pollakiuria, Increased urinary frequency, Acute renal failure, Haematuria, Micturition disorder, Nocturia, Interstitial nephritis, Renal insufficiency, Erectile dysfunction, Gynaecomastia, Asthenia, Peripheral oedema, Fatigue, Chest pain, Fever, Influenza-like symptoms, Lethargy, Malaise, Pain, Face oedema, Blood creatinine increased, Blood urea increased, Blood uric acid increased, Blood potassium decreased, Gamma glutamyl transferase increased, Gamma glutamyl transferase, Gamma glutamyl transferase increased, Aspartate aminotransferase increased, Blood creatine, Weight decrease, Weight increase, phosphokinase increased

**Manufactured by:**



TORRENT PHARMACEUTICALS LTD.

Intrad-382 721, Dist. Mehsana, INDIA.

At: 19, 20,21, Sector-6A, I.I.E;

SIDCUL, Ranipur, Haridwar- 249 403.

**IN/TRI-OLMETOR 20, 40 mg/Mar-21/06/ABPI**

(Additional information is available on request)