

## TRIOSAR

**For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only**

Abbreviated Prescribing information for TRIOSAR [Losartan Potassium, Amlodipine and Chlorthalidone Tablets]

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

### PHARMACOLOGICAL PROPERTIES:

**MECHANISM OF ACTION: Losartan:** Losartan is a synthetic oral angiotensin-II receptor (type AT1) antagonist. Angiotensin II, a potent vasoconstrictor, is the primary active hormone of the renin/angiotensin system and an important determinant of the pathophysiology of hypertension. **Amlodipine Besilate:** Amlodipine is a calcium ion influx inhibitor of the dihydropyridine group (slow channel blocker or calcium ion antagonist) and inhibits the transmembrane influx of calcium ions into cardiac and vascular smooth muscle.

**INDICATIONS:** It is used for the treatment of essential hypertension.

**DOSAGE AND ADMINISTRATION:** *Dosage:* As directed by the Physician. *Method of administration:* Tablet for oral administration.

**CONTRAINDICATION:** **1.** Hypersensitivity to the active substance, dihydropyridine derivatives, amlodipine or to any of the excipients listed. **2.** 2nd and 3rd trimester of pregnancy. **3.** Severe hepatic impairment. **4.** The concomitant use of losartan with Aliskiren-containing products is contraindicated in patients with diabetes mellitus or renal impairment (GFR < 60 ml/min/1.73 m<sup>2</sup>). **5.** Severe hypotension. **6.** Shock (including cardiogenic shock). **7.** Obstruction of the outflow tract of the left ventricle (e.g., high grade aortic stenosis). **8.** Haemodynamically unstable heart failure after acute myocardial infarction.

**WARNINGS & PRECAUTIONS: WARNING: FETAL TOXICITY.** TRIOSAR is not recommended in early pregnancy and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if used at that stage. It is important to tell your doctor before taking TRIOSAR: **1.** if you have had a history of angioedema (swelling of the face, lips, throat, and/or tongue). **2.** if you suffer from excessive vomiting or diarrhoea leading to an extreme loss of fluid and/or salt in your body **3.** if you receive diuretics (medicines that increase the amount of water that you pass out through your kidneys) or are under dietary salt restriction leading to an extreme loss of fluid and salt in your body. **4.** if you are known to have narrowing or blockage of the blood vessels leading to your kidneys or if you have received a kidney transplant recently. **5.** if your liver function is impaired. **6.** if you suffer from heart failure with or without renal impairment or concomitant severe life-threatening cardiac arrhythmias. Special caution is necessary when you are treated with a  $\beta$ -blocker concomitantly **7.** if you have problems with your heart valves or heart muscle, **8.** if you suffer from coronary heart disease (caused by a reduced blood flow in the blood vessels of the heart) or from cerebrovascular disease (caused by a reduced blood circulation in the brain), **9.** if you suffer from primary hyperaldosteronism (a syndrome associated with increased secretion of the hormone aldosterone by the adrenal gland, caused by an abnormality within the gland), **10.** if you are taking any of the following medicines used to treat high blood pressure: an ACE-inhibitor (for example enalapril, lisinopril, ramipril), in particular if you have diabetes-related kidney problems; aliskiren **11.** Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals.

**DRUG INTERACTIONS: Losartan potassium:** Tricyclic Antidepressants, Antipsychotics, Baclofen, Amifostine, Rifampicin, Fluvastatin, Potassium-Sparing Diuretics, Heparin, Lithium. **Amlodipine Besilate:** CYP3A4 Inhibitors (Protease Inhibitors, Azole Antifungals, Macrolides Like Erythromycin or Clarithromycin, Verapamil or Diltiazem), Amiloride, Triamterene, Spironolactone, CYP3A4 Inducers (e.g. Rifampicin, Hypericum Perforatum), Grapefruit or Grapefruit Juice, Dantrolene (Infusion), Tacrolimus, Mechanistic Target of Rapamycin (mTor) Inhibitors (e.g. Sirolimus, Temsirolimus, and

Everolimus), Cyclosporine, Simvastatin. **Chlorthalidone:** Guanethidine, Methyldopa,  $\beta$ -Blockers, Vasodilators, Calcium Antagonists and ACE Inhibitors, Corticosteroids, ACTH,  $\beta_2$  – Agonists, Amphotericin, Carbenoxolone, Insulin and Oral Anti-Diabetic Agents, Thiazide, Indometacin, Atropine, Biperiden, Resins e.g. Colestyramine, Cyclophosphamide, Methotrexate, Calcium Salts and Vitamin D.

**ADVERSE REACTIONS: Losartan potassium:** Anaemia, Thrombocytopenia, Hypersensitivity Reactions, Anaphylactic reactions, Angiooedema, Vasculitis, Depression, Dizziness, Somnolence, Headache, Sleep Disorders, Paraesthesia, Migraine, Dysgeusia, Vertigo, Tinnitus, Palpitations, Angina Pectoris, Syncope, Atrial Fibrillation, Cerebrovascular Accident, Hypotension, Dyspnoea, Cough, Abdominal pain, Diarrhoea, Nausea, Vomiting, Pancreatitis, Hepatitis, Liver function abnormalities, Urticaria, Rash, Pruritus, Photosensitivity, Myalgia, Arthralgia, Rhabdomyolysis, Renal impairment, Renal failure, Erectile dysfunction / Impotence, Asthenia, Fatigue, Malaise, Hyperkalaemia, Increased Alanine Aminotransferase (ALT), Increase in blood urea, Serum creatinine and Serum potassium, Hyponatraemia, Hypoglycaemia. **Amlodipine Besilate:** Leukocytopenia, Mood changes (Including Anxiety), Insomnia, Confusion, Dizziness, Tremor, Hypoaesthesia, Hypertonia, Peripheral Neuropathy, Visual Disturbance (Including Diplopia), Arrhythmia, Myocardial Infarction, Flushing, Rhinitis, Nausea, Dyspepsia, Altered Bowel Habits, Dry Mouth, Gastritis, Gingival Hyperplasia, Hepatitis, Jaundice, Hepatic Enzyme Increased, Alopecia, Purpura, Skin Discolouration, Hyperhidrosis, Exanthema, , Erythema Multiforme, Exfoliative Dermatitis, Stevens-Johnson Syndrome, , Toxic Epidermal Necrolysis, Ankle Swelling, Muscle Cramps, Back Pain, Micturition Disorder, Nocturia, Increased Urinary Frequency, Impotence, Gynaecomastia, , Fatigue, Chest Pain, Pain, Weight Increased, Weight Decreased. **Chlorthalidone:** Hyperuricaemia, And Rise In Blood Lipids, Hypomagnesaemia, Gout, Hypercalcaemia, Glycosuria, Worsening Of Diabetic Metabolic State, Hypochloroemic Alkalosis, Intrahepatic Cholestasis Or Jaundice, Postural, Cardiac Arrhythmias, Dizziness, Headache, Gastric Pain, Constipation, Leucopenia, Agranulocytosis And Eosinophilia, Impotence, Allergic Interstitial Nephritis.

**MARKETED BY:**



Torrent Pharmaceuticals Limited.

**IN/TRILOSAR 50, 5, 6.25, 12.5 mg/Feb-2025/01/ABPI**

(Additional information is available on request)