

TORCILIN TRIO

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

Abbreviated Prescribing information for TORCILIN TRIO [Cilnidipine 10 mg, Telmisartan 40 mg & Chlorthalidone 6.25 mg Tablets]

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: **Cilnidipine:** Experimental data suggest that cilnidipine binds to the dihydropyridine binding sites of the L-type voltage-dependent calcium channel and inhibits Ca²⁺ influx across the cell membranes of vascular smooth muscle cells via this channel (rabbits in vitro). Consequently, vascular smooth muscle is relaxed, causing vasodilation. Through this mechanism, cilnidipine is considered to have a hypotensive action. **Telmisartan:** is an orally active and specific angiotensin II receptor (type AT₁), antagonist. Telmisartan displaces angiotensin II with very high affinity from its binding site at the AT₁ receptor subtype, which is responsible for the known actions of angiotensin II. Telmisartan does not exhibit any partial agonist activity at the AT₁ receptor. Telmisartan selectively binds the AT₁ receptor. The binding is long-lasting. Telmisartan does not show an affinity for other receptors, including AT₂ and other less characterized AT receptors. The functional role of these receptors is not known, nor is the effect of their possible overstimulation by angiotensin II, whose levels are increased by Telmisartan. **Chlorthalidone:** Chlorthalidone is a benzothiadiazine (thiazide)-related diuretic, chemically related to the sulphonamides, with a long duration of action. Thiazide and thiazide-like diuretics act primarily on the distal renal tubule (early convoluted part), inhibiting NaCl reabsorption (by antagonising the Na⁺ -Cl⁻ cotransporter) and promoting Ca⁺⁺ reabsorption (by an unknown mechanism). The enhanced delivery of Na⁺ and water to the cortical collecting tubule and/or the increased flow rate leads to increased secretion and excretion of K⁺ and H⁺.

INDICATIONS: It is indicated for the treatment of essential hypertension.

DOSAGE AND ADMINISTRATION: As directed by the Physician. The recommended adult oral dosage of Torcilin Trio is one tablet per day. Torcilin Trio may be administered in patients whose Blood Pressure (BP) is not adequately controlled with monotherapy of cilnidipine/telmisartan/chlorthalidone or dual therapy. Tablet for oral administration.

CONTRAINDICATION: Cardiogenic shock, Recent MI or acute unstable angina, Severe aortic stenosis, Known hypersensitivity to active ingredients or any of the excipients, Anuria, severe hepatic or renal failure (creatinine clearance <30ml/min), Hypersensitivity to chlorthalidone and other sulphonamide derivatives, Refractory hypokalaemia, hyponatremia and hypercalcemia, symptomatic hyperuricemia (history of gout or uric acid calculi), Pregnancy, Untreated Addison's disease, Concomitant lithium therapy, Biliary obstructive disorders, The concomitant use of Telmisartan with aliskiren-containing products is contraindicated in patients with diabetes mellitus or renal impairment (GFR < 60 ml/min/1.73 m²).

WARNINGS & PRECAUTIONS: **Cilnidipine:** Careful Administration (cilnidipine should be administered with care in the following patients.): Patients with serious hepatic dysfunction [The plasma concentration may become elevated]. Patients with a history of serious adverse reactions to calcium antagonists. Elderly patients: Cilnidipine should be administered carefully under close observation of the patient's condition, taking such measures as starting with a lower dose (e.g. 5 mg). Use in the Elderly is generally acknowledged that excessive hypotensive action should be avoided in the elderly. **Telmisartan:** *Pregnancy:* Angiotensin II receptor antagonists should not be initiated during pregnancy. Unless continued angiotensin II receptor antagonist therapy is considered essential, patients planning pregnancy should be changed to alternative antihypertensive treatments which have an established safety profile for use in pregnancy. When pregnancy is diagnosed, treatment with angiotensin II receptor antagonists should be stopped immediately. *Renovascular hypertension:* There is an increased risk of severe hypotension and renal insufficiency when patients with bilateral renal artery stenosis or stenosis of the artery to a single functioning kidney are treated with medicinal products that affect the rennin angiotensin aldosterone system. *Renal impairment and kidney transplantation:* When Telmisartan is used in patients with impaired renal function, periodic monitoring of potassium and creatinine serum levels is recommended. There is no experience regarding the administration of Telmisartan in patients with recent kidney transplantation. *Intravascular hypovolaemia:* Symptomatic hypotension, especially after the first dose of Telmisartan, may occur in patients who are volume and/or sodium depleted by vigorous diuretic therapy, dietary

salt restriction, diarrhea, or vomiting. Such conditions should be corrected before the administration of Telmisartan. **Chlorthalidone:** Plasma electrolyte should be periodically determined at inappropriate intervals to detect possible electrolyte imbalance especially hypokalaemia and hyponatraemia, Hypokalaemia and hyponatraemia may occur. Measurement of electrolytes is recommended, especially in the older patient, those receiving digitalis preparations for cardiac failure, those taking an abnormal (low in potassium) diet, or those suffering from gastrointestinal complaints. Hypokalaemia may predispose to arrhythmias in patients receiving digitalis. Impaired glucose tolerance may occur, and diabetic patients should be aware of the potential for increased glucose levels.

DRUG INTERACTIONS: **Cilnidipine:** Cilnidipine is chiefly metabolized by the drug-metabolizing enzyme CYP3A4 and in part by CYP2C19. Other antihypertensive drugs Additive or synergistic potentiation of the effect has been implicated Digoxin, Cimetidine, Rifampicin, Antifungal azoles: Itraconazole, Miconazole etc. **Telmisartan:** Digoxin, Potassium-sparing diuretics or potassium supplement, Lithium, NSAIDs, Diuretics (thiazide or loop diuretics). **Chlorthalidone:** Diuretics may reduce lithium excretion and thus increase its plasma levels. Since diuretics raise blood lithium levels, the latter must be monitored in patients under lithium therapy who are taking Chlorthalidone at the same time.

ADVERSE REACTIONS: **Telmisartan:** Serious adverse drug reactions include anaphylactic reaction, angioedema which may occur rarely ($\geq 1/10,000$ to $< 1/1,000$), and acute renal failure. Urinary tract infection including cystitis, Anaemia, Visual disturbance, Hypotension, orthostatic hypotension. **Cilnidipine:** Hepatic function disorder and jaundice accompanied by increased AST (GOT), ALT (GPT), and γ -GTP may occur, Thrombocytopenia (incidence: $< 0.1\%$): Since thrombocytopenia may occur, close observation should be made, and if any abnormality is observed, appropriate measures, such as discontinuation of cilnidipine, should be taken, Headache, Headache dull, Dizziness, Oedema. **Chlorthalidone:** Hypokalaemia, hyperuricaemia, and hyperlipidaemia, dizziness, vertigo, weakness, erectile dysfunction, hyponatraemia, hypomagnesaemia, hyperglycaemia and decreased appetite.

MARKETED BY:



Torrent Pharmaceuticals Limited.

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(Additional information is available on request)