TORCILIN–T

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

Abbreviated Prescribing information for **TORCILIN–T** [Telmisartan 40 mg and Cilnidipine 10 mg tablets] [Please refer the complete prescribing information available at www.torrentpharma.com] **PHARMACOLOGICAL PROPERTIES**: Telmisartan blocks the vasoconstrictor and aldosterone secreting effects of angiotensin II by selectively blocking the binding of angiotensin II to the AT_1 receptor in many tissues, such as vascular smooth muscle and the adrenal gland. Cilnidipine blocks the influx of Ca^{2+} ions into both vascular smooth muscle at the level of L-type Ca^{2+} channels and neuronal cells at the level of N-type Ca^{2+} channels. The L-type Ca^{2+} channel blockade by cilnidipine affects predominantly vascular smooth muscle, thereby producing vasodilation of peripheral resistance vessels and coronary arteries. **INDICATION**: Torcilin-T is indicated for the treatment of hypertension. **DOSAGE AND ADMINISTRATION**: Dosage must be individualized. Starting dose is one tablet once a day or as directed by physician. Torcilin-T may be administered with or without food. Torcilin-T is usually recommended after breakfast. **CONTRAINDICATION:** Contraindicated in patients with known hypersensitivity (e.g., anaphylaxis or angioedema) to telmisartan or cilinidipine or any other component of this product. Cilnidipine should not be administered in pregnant women and women suspected of being pregnant. Cardiogenic shock, recent MI or acute unstable angina and severe aortic stenosis. Cilnidipine should carefully administration in blood concentration raises patients with severe hepatic dysfunction and history of adverse reactions suffered from calcium antagonist. **WARNINGS & PRECAUTIONS**: The use of telmisartan during the 2nd and 3rd trimesters of pregnancy has been associated with fetal and neonatal injury, including hypotension, neonatal skull hypoplasia, symptomatic hypotension, anuria, reversible or irreversible renal failure and death. Oligohydramnios has reported, presumably resulting from decreased fetal renal function, oligohydramnios in this setting has been associated with fetal limb contractures, craniofacial deformation and hypoplastic lung development. Caution should be exercised in patients with biliary obstructive disorders or hepatic insufficiency. Dual blockade of the RAS with angiotensin receptor blockers, ACE inhibitors, or aliskiren is associated with increased risks of hypotension, hyperkalemia, and changes in renal function (including acute renal failure) compared to monotherapy. Cilinidipine sudden withdrawal may exacerbate angina. Cilinidipine discontinue in patients who experience ischemic pain, hypotension, poor cardiac reserve and heart failure following administration. Patient may feel dizziness due to decrease the pressure. So, do not work at height, drive a car or operate heavy machinery while taking this medicine. An ingredient in grapefruit juice may intensify the medicine's effect. Administrations of calcium antagonists suddenly stop; the patients develop the symptoms have been reported. **DRUG INTERACTIONS**: Telmisartan may interact with digoxin, warfarin, aliskiren, lithium, ramipril and co-administration of NSAIDs including selective COX-2 inhibitors. Quinidine, carbamazepine, phenytoin, rifampicin, cimetidine and erythromycin are also interacted with the cilnidipine. **ADVERSE REACTIONS**: headache, dizziness, asthenia, coughing, nausea, fatigue, weakness, edema, face edema, lower limb edema, angioneurotic edema, urticaria, hypersensitivity, sweating increased, erythema, chest pain, atrial fibrillation, congestive heart failure, myocardial infarction, blood pressure increased, hypertension aggravated, hypotension (including postural hypotension), hyperkalemia, syncope, dyspepsia, diarrhea, pain, urinary tract infection, erectile dysfunction, back pain, abdominal pain, muscle cramps (including leg cramps), myalgia, bradycardia, eosinophilia, thrombocytopenia, uric acid increased, abnormal hepatic function/liver disorder, renal impairment including acute renal failure, anemia, increased CPK, anaphylactic reaction, tendon pain (including tendonitis, tenosynovitis), drug eruption (toxic skin eruption mostly reported as toxicoderma, rash, and urticaria), hypoglycemia (in diabetic patients) and angioedema (with fatal outcome).

MARKETED BY:

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IN/ TORCILIN–T 40mg,10mg /JUN-2016/01/ABPI
(Additional information is available on request)