

TORCILIN-T

For the use of a Registered Medical Practitioner or a 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]

WARNING: FETAL TOXICITY

- When pregnancy is detected, discontinue the product as soon as possible.
- Drugs that act directly on the renin-angiotensin system can cause injury and death to the developing fetus.

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: *Telmisartan*: 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. *Cilnidipine*: Cilnidipine inhibits the transmembrane influx of calcium ions (Ca⁺⁺) into cardiac and vascular smooth muscle. Antihypertensive action of cilnidipine is due to a direct relaxant effect on vascular smooth muscle.

INDICATIONS: Torcilin-T is indicated for the treatment of hypertension.

DOSAGE AND ADMINISTRATION: The usual dose is 1 tablet of Torcilin-T to be administered once daily. The tablet should be swallowed whole with water. Torcilin-T may be administered with or without food. Torcilin-T is usually recommended after breakfast.

CONTRAINDICATION: • Hypersensitivity to cilnidipine or to telmisartan or to any component of the •Formulation. •cardiogenic shock. •Severe aortic stenosis. •Recent history of unstable angina or acute myocardial infarction, heart failure, •Hypotension. •Second and third trimesters of pregnancy. •Severe hepatic impairment and 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: *Telmisartan*: Angiotensin II receptor antagonists should not be initiated during pregnancy. When pregnancy is diagnosed, treatment with angiotensin II receptor antagonists should be stopped immediately, and, if appropriate, alternative therapy should be started. Telmisartan is not to be given to patients with cholestasis, biliary obstructive disorders, or severe hepatic impairment since telmisartan is mostly eliminated with the bile. 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 renin-angiotensin-aldosterone system. When Telmisartan is used in patients with impaired renal function, periodic monitoring of potassium and creatinine serum levels is recommended. 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, diarrhoea or vomiting. ACE-inhibitors and angiotensin II receptor blockers should not be used concomitantly in patients with diabetic nephropathy. the use of telmisartan is not recommended in primary aldosteronism. special caution is indicated in patients suffering from aortic or mitral stenosis, or obstructive hypertrophic cardiomyopathy. In diabetic patients treated with insulin or antidiabetics hypoglycaemia may occur under telmisartan treatment. *Cilnidipine*: Cilnidipine should be used with caution in patients with hypotension, heart failure, and poor cardiac reserve. It should be discontinued immediately in patients who feel chest pain following the administration of the drug. In case of angina, cilnidipine should not be discontinued abruptly to avoid withdrawal symptoms. Grapefruit juice may intensify the effect of cilnidipine. Thus, avoid drinking grapefruit juice as much as possible while on cilnidipine therapy.

DRUG INTERACTIONS: *Telmisartan:* Monitor digoxin levels when initiating, adjusting, and discontinuing telmisartan for the purpose of keeping the digoxin level within the therapeutic range. If concomitant use with potassium sparing diuretics is indicated because of documented hypokalaemia they should be used with caution and with frequent monitoring of serum potassium. Reversible increases in serum lithium concentrations and toxicity have been reported during concomitant administration of lithium with angiotensin converting enzyme inhibitors, and, with angiotensin II receptor antagonists. NSAIDs (i.e. acetylsalicylic acid at anti-inflammatory dosage regimens, COX-2 inhibitors and non-selective NSAIDs) and corticosteroids may reduce the antihypertensive effect of angiotensin II receptor antagonists. *Cilnidipine:* Co-administration of antipsychotic drugs with cilnidipine may result in low blood pressure. Co-administration of cilnidipine with antidiabetic drugs may result in changes in glucose levels. Antiepileptic drugs (such as phenytoin and carbamazepine), rifampin, quinidine, erythromycin, other anti-hypertensive drugs, and aldesleukin should also be used with caution along with cilnidipine.

ADVERSE REACTIONS: Anaphylactic reaction, sepsis including fatal, infection including cystitis, upper respiratory tract infection including pharyngitis and sinusitis, anaemia, eosinophilia, thrombocytopenia, hypersensitivity, hyperkalaemia, hypoglycaemia, insomnia, depression, anxiety, syncope, somnolence, visual disturbance, vertigo, bradycardia, tachycardia, hypotension, orthostatic hypotension, dyspnoea, cough, interstitial lung disease, abdominal pain, diarrhoea, dyspepsia, flatulence, vomiting, dry mouth, stomach discomfort, dysgeusia, hepatic function abnormal/liver disorder, pruritus, hyperhidrosis, rash, angioedema (also with fatal outcome), eczema, erythema, urticaria, drug eruption, toxic skin eruption, back pain (e.g. sciatica), muscle spasms, arthralgia, pain in extremity, tendon pain (tendinitis like symptoms), renal impairment including acute renal failure, chest pain, asthenia, influenza-like illness, blood creatinine increased, haemoglobin decreased, blood uric acid increased, creatine phosphokinase increased, edema (face, limb, etc.), facial flush, thickening of gums, heat sensation, lethargy, generalized fatigue, frequent urination, impotence, transient blindness, eye pain, muscle ache, tremors, palpitations, ischemic chest pain, cerebral ischemia, itching, and photosensitivity.

MARKETED BY:

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(Additional information is available on request)