TELDAY CH

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

Abbreviated Prescribing information for TELDAY CH (Telmisartan 40/80mg and Chlorthalidone 12.5mg)[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Telday CH is a fixed-dose combination of telmisartan, an orally active angiotensin II antagonist acting on the AT1 receptor subtype, and chlorthalidone, a thiazide-like diuretic. Thus, the two drugs target two separate mechanisms involved in blood pressure regulation and hence may provide additive blood pressure reduction. **INDICATION:** Indicated for the treatment of hypertension, to lower blood pressure in patients not adequately controlled with monotherapy. **DOSAGE AND ADMINISTRATION:** The usual initial dosage is one tablet orally once daily. The dose may be increased to two tablets of Telday CH 40 or Telday CH 80 once daily according to physician's discretion if blood pressure remains uncontrolled after 2-4 weeks of therapy. **CONTRAINDICATION:** In patients with known hypersensitivity (e.g., anaphylaxis or angioedema) to telmisartan, chlorthalidone, or any other component of this product. Because of the chlorthalidone component, this product is contraindicated in patients with anuria or hypersensitivity to other sulfonamide-derived drugs. Do not co-administer aliskiren with Telday CH in patients with diabetes. **WARNINGS & PRECAUTIONS**: **Telmisartan**: When pregnancy is detected, Telmisartan should be discontinued as soon as possible. The use of drugs that act directly on the renin angiotensin system during the second and third 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 also been 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. In patients with an activated renin-angiotensin system, such as volume- or salt-depleted patients (e.g., those being treated with high doses of diuretics), symptomatic hypotension may occur after initiation of therapy with Telmisartan. Hyperkalemia may occur in patients on ARBs, particularly in patients with advanced renal impairment, heart failure, on renal replacement therapy, or on potassium supplements, potassium-sparing diuretics, potassium-containing salt substitutes or other drugs that increase potassium levels. Caution should be exercised in patients with biliary obstructive disorders or hepatic insufficiency. Impaired Renal Function, 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. **Chlorthalidone:** Fetal toxicity, azotemia, hypokalemia, and hyperuricemia. **DRUG INTERACTIONS:** Digoxin, warfarin, lithium, aliskiren**,** ramipril, NSAIDS, nondepolarizing skeletal muscle relaxants, (eg, Tubocurarine) and Pressor Amines (eg, Norepinephrine). Dosage adjustment of the antidiabetic drug may be required. **ADVERSE REACTIONS:** Renal dysfunction upon use with ramipril, impotence, increased sweating, flushing, upper respiratory tract infection, allergy, fever, leg pain, malaise, palpitation, angina pectoris, tachycardia, leg edema, abnormal ECG, insomnia, somnolence, migraine, vertigo, paresthesia, involuntary muscle contractions, hypoaesthesia, flatulence, anorexia, gastric irritation, gastrointestinal (GI) upset, aplastic anemia. purpura, photosensitivity, rash, urticaria, Orthostatic hypotension may occur and may be aggravated by alcohol, barbiturates or narcotics. Hyperglycemia, glycosuria, hyperuricemia, hypercholesterolemia, muscle spasm, nausea, vomiting, cramping, diarrhea, constipation, jaundice , gastritis, vomiting, dry mouth, hemorrhoids, gastroenteritis, gastroesophageal reflux, toothache, non-specific gastrointestinal disorders, gout, hypercholesterolemia, diabetes mellitus, arthritis, arthralgia, leg cramps, anxiety, depression, asthma, bronchitis, rhinitis, dyspnea, epistaxis, dermatitis, rash, eczema, pruritus, micturition frequency, cystitis, cerebrovascular disorders abnormal vision, conjunctivitis, tinnitus and ear ache. uric acid increased, abnormal hepatic function/liver disorder, anemia and increased CPK.

MARKETED BY:

TORRENT PHARMACEUTICALS LTD.
Torrent House, Off Ashram Road,
Ahmedabad-380 009, INDIA
IN/TELDEY CH /40,80,12.5mg/Aug-15/01/AbPI
(Additional information is available on request)