TELDAY H

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

Abbreviated Prescribing information for TELDAY H (**Telmisartan 40mg and Hydrochlorothiazide 12.5mg 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 AT1 receptor and Hydrochlorothiazide is a thiazide diuretic. **INDICATION:** For the treatment of hypertension. **DOSAGE AND ADMINISTRATION:** The recommended dose of TELDAY-H tablets is once a day. TELDAY-H can be administered with other antihypertensives. TELDAY-H can be administered with or without food. **CONTRAINDICATION:** In patients who are hypersensitive to any component of this product, in patients with anuria or hypersensitivity to other sulfonamide-derived drugs because of hydrochlorothiazide component of product, second and third trimesters of pregnancy, cholestasis, biliary obstructive disorders, severe hepatic impairment. severe renal impairment (creatinine clearance <30 ml/min), refractory hypokalaemia and hypercalcaemia. **WARNINGS & PRECAUTIONS**: 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. 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. **Hydrochlorothiazide:** Caution should be exercised in hepatic impairment, hypersensitivity reaction, systemic lupus erythematosus, lithium interaction, acute myopia and secondary angle-closure glaucoma. **DRUG INTERACTIONS:** Medicinal products associated with potassium loss and hypokalaemia (e.g. other kaliuretic diuretics, laxatives, corticosteroids, ACTH, amphotericin, carbenoxolone, penicillin G sodium, salicylic acid and derivatives), Medicinal products affected by serum potassium disturbances (e.g. digitalis glycosides, antiarrhythmics). **Telmisartan**: digoxin, warfarin, lithium, NSAIDS and ramipril. **Hydrochlorothiazide:-** Alcohol, barbiturates, or narcotics, antidiabetic drugs (oral agents and insulin), cholestyramine and colestipol resins, Medicinal products used in the treatment for gout (e.g. probenecid, sulfinpyrazone and allopurinol), Thiazide diuretics may increase serum calcium levels due to the decreased excretion. Beta-blockers and diazoxide, Amantadine, Cytotoxic agents (e.g. cyclophosphamide, methotrexate), corticosteroids, ACTH, pressor amines (e.g., norepinephrine), skeletal muscle relaxants, nondepolarizing (e.g., tubocurarine), Metformin should be used with precaution as risk of lactic acidosis induced by a possible functional renal failure linked to hydrochlorothiazide. **ADVERSE REACTIONS:** Impotence, increased sweating, flushing, fever, leg pain, malaise, palpitation, dependent edema, angina pectoris, tachycardia, leg edema, abnormal ECG, insomnia, somnolence, migraine, vertigo, paresthesia, involuntary muscle contractions, hypoaesthesia, flatulence, constipation, gastritis, vomiting, dry mouth, hemorrhoids, gastroenteritis, enteritis, gastroesophageal reflux, toothache, non-specific gastrointestinal disorders, gout, hypercholesterolemia, diabetes mellitus, arthritis, arthralgia, leg cramps, anxiety, depression, nervousness, asthma, bronchitis, rhinitis, dyspnea, epistaxis, dermatitis, rash, eczema, pruritus, micturition frequency, cystitis, cerebrovascular disorder, abnormal vision, conjunctivitis, tinnitus, earache, pancreatitis, jaundice

(intrahepatic cholestatic jaundice), sialadenitis, cramping, gastric irritation, aplastic anemia, agranulocytosis, leukopenia, hemolytic anemia, thrombocytopenia, purpura, photosensitivity, urticaria, necrotizing angiitis (vasculitis and cutaneous vasculitis), fever, respiratory distress including pneumonitis and pulmonary edema, anaphylactic reactions, renal failure, erythema multiforme including Stevens-Johnson syndrome, increased CPK, anaphylactic reaction and tendon pain.

MARKETED BY:

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(Additional information is available on request)