TELDAY-H/80 H

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

Abbreviated Prescribing information for TELDAY-H/80 H [Telmisartan and Hydrochlorothiazide Tablets I.P.]

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

PHARMACOLOssGICAL PROPERTIES:

MECHANISM OF ACTION: Telmisartan is an orally effective and specific angiotensin II receptor subtype 1 (AT1) blockers. 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 affinity for other receptors, including AT2 and other less characterised 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. Plasma aldosterone levels are decreased by telmisartan. Telmisartan does not inhibit human plasma renin or block ion channels. Telmisartan does not inhibit angiotensin converting enzyme (kininase II), the enzyme which also degrades bradykinin. Therefore, it is not expected to potentiate bradykinin-mediated adverse effects. Hydrochlorothiazide is a thiazide diuretic. The mechanism of the antihypertensive effect of thiazide diuretics is not fully known. Thiazides have an effect on the renal tubular mechanisms of electrolyte reabsorption, directly increasing excretion of sodium and chloride in approximately equivalent amounts. The diuretic action of hydrochlorothiazide reduces plasma volume, increases plasma renin activity, increases aldosterone secretion, with consequent increases in urinary potassium and bicarbonate loss, and decreases in serum potassium. Presumably through blockade of the reninangiotensin aldosterone system, co-administration of telmisartan tends to reverse the potassium loss associated with these diuretics. With hydrochlorothiazide, onset of diuresis occurs in 2 hours, and peak effect occurs at about 4 hours, while the action persists for approximately 6-12 hours.

INDICATIONS: Fixed dose combination of Telmisartan and Hydrochlorothiazide is indicated for the treatment of hypertension as second line therapy.

DOSAGE AND ADMINISTRATION: Telmisartan and Hydrochlorothiazide Tablets are for once-daily oral administration and should be taken with liquid, with or without food. . Individual dose titration with each of the two components is recommended before changing to the fixed dose combination. When clinically appropriate, direct change from monotherapy to the fixed combination may be considered.

CONTRAINDICATION: Hypersensitivity to the active substance or to any of the excipients. Hypersensitivity to other sulphonamide-derived substances (since hydrochlorothiazide is a sulphonamide-derived medicinal product). Second and third trimesters of pregnancy. Cholestasis and biliary obstructive disorders. Severe hepatic impairment. Severe renal impairment (creatinine clearance < 30 ml/min), Anuria. Refractory hypokalaemia, hypercalcaemia.

WARNINGS & PRECAUTIONS: Angiotensin II receptor blockers should not be initiated during pregnancy. Unless continued angiotensin II receptor blockers 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 blockers should be stopped immediately, and, if appropriate, alternative therapy should be started. Telmisartan and Hydrochlorothiazide Tablets should not be given to patients with cholestasis, biliary obstructive disorders or severe hepatic insufficiency 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. Dual blockade of RAAS through the combined use of ACE-inhibitors, angiotensin II receptor blockers or aliskiren is

therefore not recommended. An increased risk of non-melanoma skin cancer (NMSC) [basal cell carcinoma (BCC) and squamous cell carcinoma (SCC)] with increasing cumulative dose of hydrochlorothiazide (HCTZ) exposure has been observed in two epidemiological studies based on the Danish National Cancer Registry. Photosensitizing actions of HCTZ could act as a possible mechanism for NMSC.

DRUG INTERACTIONS: When telmisartan was co-administered with digoxin, median increases in digoxin peak plasma concentration (49%) and in trough concentration (20%) were observed. When initiating, adjusting, and discontinuing telmisartan, monitor digoxin levels in order to maintain levels within the therapeutic range. Metformin should be used with precaution: risk of lactic acidosis induced by a possible functional renal failure linked to hydrochlorothiazide. Thiazides may reduce the renal excretion of cytotoxic medicinal products and potentiate their myelosuppressive effects. Dosage adjustment of uricosuric medications may be necessary as hydrochlorothiazide may raise the level of serum uric acid. Increase in dosage of probenecid or sulfinpyrazone may be necessary. Co-administration of thiazide may increase the incidence of hypersensitivity reactions of allopurinol.

ADVERSE REACTIONS: Brobchitis, pharyngitis, sinusitis, hypokalemia, anxiety, depression, insomnia, hyperuricemia, hyponatremia, sleep disorders, dizziness, syncope, paraesthesia, visual disturbance/ impairment, vision blurred, vertigo, tachycardia, arrhythmias, hypotension, orthostatic hypotension, dyspnoea, respiratory distress, pneumonitis, pulmonary oedema, diarrhoea, dry mouth, flatulence, abdominal pain, constipation, , vomiting, gastritis, abnormal hepatic function/liver disorder, angioedema, pruritus, erythema, rash, hyperhidrosis, urticaria, back pain, muscle spasms, myalgia, arthralgia, muscle cramps, pain in limb/leg extremities, systemic lupus erythematous, erectile dysfunction, chest pain, influenza illness, pain, blood uric acid increase, blood creatinine increased, blood creatine phosphokinase increased hepatic enzyme increased. upper respiratory tract infection, urinary tract infection including cystitis, sepsis including fatal outcome, anaemia, eosinophilia, thrombocytopenia, hypoglycaemia, bradycardia, somnolence, vertigo, cough, interstitial lung disease, eczema, drug eruption, toxic skin eruption, hepatobiliary disorders abdominal hepatic function/liver disorder, vasculitis necrotizing, erythema multiforme

MARKETED BY:

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Torrent Pharmaceuticals Limited.

IN/TELDAY H/80H 40/12.5, 80/12.5/MAY 2026/07/ABPI

(Additional information is available on request)