TELDAY H/ 80 H

For the use of a Registered Medical Practitioner or 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]

PHARMACOLOGICAL PROPERTIES:

Mechanism of action: 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. Hydrochlorothiazide 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.

DOSAGE AND ADMINISTRATION: As directed by physician.

CONTRAINDICATION: Hypersensitivity to any of the active substances 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). Refractory hypokalaemia, hypercalcaemia. The concomitant use of Telmisartan & Hydrochlorothiazide with aliskiren-containing products is contraindicated in patients with diabetes mellitus or renal impairment (GFR < 60 ml/min/1.73 m^2).

WARNINGS & PRECAUTIONS: Pregnancy, Hepatic impairment, Renovascular hypertension, Renal impairment and kidney transplantation, Intravascular hypovolaemia, Dual blockade of the renin-angiotensin-aldosterone system (RAAS), Other conditions with stimulation of the renin-angiotensin-aldosterone system, Primary aldosteronism, Aortic and mitral valve stenosis, obstructive hypertrophic cardiomyopathy, Metabolic and endocrine effects, Electrolyte imbalance, Lactose Monohydrate, Ethnic differences, Choroidal effusion, Acute Myopia and Angle-Closure Glaucoma, Non-melanoma skin cancer.

DRUG INTERACTION: Lithium, 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 that may increase potassium levels or induce hyperkalaemia (e.g. ACE inhibitors, potassium-sparing diuretics, and potassium supplements, salt substitutes containing potassium, cyclosporin or other medicinal products such as heparin sodium), Medicinal products affected by serum potassium disturbances, Digitalis glycosides, Digoxin, Other antihypertensive agents, Antidiabetic medicinal products (oral agents and insulin), Cholestyramine and colestipol resins, Non-steroidal anti-inflammatory medicinal products, Pressor amines (e.g. noradrenaline), Non depolarizing skeletal muscle relaxants (e.g. tubocurarine), Medicinal products used in the treatment for gout (e.g. probenecid, sulfinpyrazone and allopurinol), Calcium salts, Beta-blockers and diazoxide, Anticholinergic agents (e.g. atropine, biperiden), Amantadine, Cytotoxic agents (e.g. cyclophosphamide, methotrexate).

ADVERSE REACTIONS: Bronchitis, pharyngitis, sinusitis, Exacerbation or activation of systemic lupus erythematosus, Hypokalaemia, Hyperuricaemia, hyponatraemia, Anxiety,

Depression, Dizziness, Syncope, paraesthesia, Insomnia, sleep disorders, Visual disturbance, vision blurred, Vertigo, Tachycardia, arrhythmias, Hypotension, orthostatic hypotension, Diarrhoea, dry mouth, flatulence, Abdominal pain, constipation, dyspepsia, vomiting, gastritis, Abnormal hepatic function/liver disorder, Angioedema (also with fatal outcome), erythema, pruritus, rash, hyperhidrosis, urticarial, Back pain, muscle spasms, myalgia, Arthralgia, muscle cramps, pain in limb, Erectile dysfunction, Chest pain, Influenza-like illness, pain, Blood uric acid increased, 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, anaphylactic reactions, Hypersensitivity, Hypoglycaemia (in diabetic patients), Bradycardia, Somnolence, Cough, Interstitial lung disease, Stomach discomfort, Eczema, drug eruption, toxic skin eruption, Arthrosis, tendon pain, Renal impairment (including acute renal failure), Asthenia, Haemoglobin decreased, Sialadenitis, Non-melanoma skin cancer, Hypochloraemic alkalosis, Anorexia, appetite decreased, electrolyte imbalance, Restlessness, Headache, Light-headedness, Xanthopsia, acute myopia, acute angle-closure glaucoma, Choroidal effusion, Vasculitis necrotizing, Nausea, Pancreatitis, stomach discomfort, Jaundice hepatocellular, jaundice cholestatic, Lupus-like syndrome, photosensitivity reactions, skin vasculitis, toxic epidermal necrolysis, erythema multiforme, Weakness, Nephritis interstitial, renal dysfunction, glycosuria, Pyrexia, Triglycerides increased.

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IN/TELDAY H, 80 H 40/12.5, 80/12.5/APR 21/06/ABPI
(Additional information is available on request)