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

Abridged Prescribing Information

Telmisartan & Hydrochlorothiazide Tablets IP 40mg/ 12.5mg
Telmisartan & Hydrochlorothiazide Tablets IP 80mg/ 12.5mg
TELSITE® H

Composition: Each uncoated bilayered tablet contains Telmisartan IP 40mg/80mg + Hydrochlorothiazide IP 12.5 mg Excipients qs
Indications: Telsite H is indicated for the treatment of essential hypertension as second line therapy.
Posology and Method of Administration: *Adults : S*hould be taken once daily orally, in patients whose blood pressure is not adequately controlled by telmisartan alone. 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.
Special Populations: *Pediatric patients : S*afety and efficacy not established in children and adolescents aged below 18. *Elderly patients :* No dose adjustment is necessary. *Hepatic impairment :* In patients with mild to moderate hepatic impairment the posology should not exceed telmisartan/hydrochlorothiazide 40 mg/12.5 mg once daily. Not indicated in patients with severe hepatic impairment. Thiazides should be used with caution in patients with impaired hepatic function. *Renal impairment :* Periodic monitoring of renal function is advised.
Contraindications : Hypersensitivity to any of the active substances or to any of the excipients, hypersensitivity to other sulphonamide-derived substances, second and third trimesters of pregnancy, cholestasis and biliary obstructive disorders, severe hepatic impairment, severe renal impairment (creatinine clearance <30 ml/min), refractory hypokalemia, hypercalcemia, concomitant use with aliskiren-containing products is contraindicated in patients with diabetes mellitus or renal impairment (GFR <60 ml/min/1.73 m^2).
Special warnings and precautions for use: Hepatic impairment: Should not be given to patients with cholestasis, biliary obstructive disorders or severe hepatic insufficiency. Should be used with caution in patients with impaired hepatic function or progressive liver disease.
Renovascular hypertension: 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.
Renal impairment and kidney transplantation: Must not be used in patients with severe renal impairment.
Intravascular hypovolemia: Symptomatic hypotension, especially after the first dose, may occur in patients who are volume and/or sodium depleted by vigorous diuretic therapy, dietary salt restriction, diarrhea or vomiting.
Dual blockade of the renin-angiotensin-aldosterone system (RAAS): Concomitant use of ACE-inhibitors, angiotensin II receptor blockers, or aliskiren increases the risk of hypotension, hyperkalemia, and decreased renal function (including acute renal failure).
Other conditions with stimulation of the renin-angiotensin-aldosterone system: In patients whose vascular tone and renal function depend predominantly on the activity of the renin-angiotensin-aldosterone system, treatment may be associated with acute hypotension, hypercarotenemia, oliguria, or rarely acute renal failure.
Primary aldosteronism: Not recommended.
Aortic and mitral valve stenosis, obstructive hypertrophic cardiomyopathy: Special caution is indicated.
Metabolic and endocrine effects: Patients should consider blood glucose monitoring, a dose adjustment of insulin or antidiabetics may be required, when indicated.
Electrolyte imbalance: Periodic determination of serum electrolytes should be performed.
Ethnic differences: Telmisartan is apparently less effective in lowering blood pressure in black patients than in non-blacks.
Other: Excessive reduction of blood pressure in patients with ischemic cardiopathy or ischemic cardiovascular disease could result in a myocardial infarction or stroke.
General: Hypersensitivity reactions
Acute Respiratory Toxicity: Severe cases of acute respiratory toxicity, including acute respiratory distress syndrome (ARDS) have been reported after taking hydrochlorothiazide.
Nonmelanoma skin cancer: An increased risk of nonmelanoma skin cancer (NMSC)
Choroidal effusion, acute myopia and angle-closure glaucoma: Can cause an idiosyncratic reaction, resulting in choroidal effusion with visual field defect, acute transient myopia and acute angle-closure glaucoma.
Pregnancy: Not recommended during the 1st trimester, contraindicated during the 2nd and 3rd trimesters of pregnancy
Lactation: Not recommended and alternative treatments with better established safety profiles during breastfeeding are preferable, especially while nursing a newborn or preterm infant.
Undesirable effects: The most common reported adverse reaction is dizziness. Serious angioedema may occur rarely.

For full prescribing information please write to: Sanofi India Ltd., Sanofi House, CT Survey No 117-B, L&T Business Park, Saki Vihar Road, Powai, Mumbai 400072

Reference: Telmisartan/Hydrochlorothiazide-CCDS-v04 dated 09-Feb-2023
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