For the use only of a Registered Medical Practitioner or hospital or a laboratory

Abridged Prescribing Information

TELSITE® H
Telmisartan & Hydrochlorothiazide Tablets IP

COMPOSITION : Telsite H 40/ 80: Each uncoated bilayered tablet contains telmisartan IP 40mg/80mg + Hydrochlorothiazide IP 12.5 mg

THERAPEUTIC INDICATIONS : Indicated for the treatment of essential hypertension as second line therapy.

DOSAGE AND ADMINISTRATION : Initiate a patient whose blood pressure is not adequately controlled with telmisartan monotherapy 80 mg on Telsite H, 80 mg/12.5 mg once daily. Dose can be titrated up to 160 mg/25 mg after 2 to 4 weeks, if necessary. Initiate a patient whose blood pressure is not adequately controlled by 25 mg once daily of hydrochlorothiazide, or is controlled but who experiences hypokalemia with this regimen on Telsite H 80 mg /12.5 mg once daily. Dose can be titrated up to 160 mg/25 mg after 2 to 4 weeks, if necessary. Patients titrated to the individual components (telmisartan and hydrochlorothiazide) may instead receive the corresponding dose of Telsite H.

SAFETY RELATED INFORMATION
Contraindications : Contraindicated in patients with known hypersensitivity to any other component of the product; in patients with anuria and for co-administration with aliskiren in patients with diabetes.
Warnings and Precautions: ***Fetal Toxicity :*** Use of drugs that act on the renin-angiotensin system during the 2nd and 3rd trimesters of pregnancy reduces fetal renal function and increases fetal and neonatal morbidity and death. Thiazides cross the placental barrier and appear in cord blood. Adverse reactions include fetal or neonatal jaundice, thrombocytopenia. ***Hypotension in Volume-Depleted Patients :*** In patients with an activated renin-angiotensin system, such as volume- or salt-depleted patients symptomatic hypotension may occur. Correct volume or salt depletion prior to administration of Telsite H. ***Impaired Renal Function :*** Changes in renal function including acute renal failure can be caused by drugs that inhibit the renin-angiotensin system and by diuretics. Monitor renal function periodically in these patients. ***Electrolytes and Metabolic Disorders :*** Drugs that inhibit the renin-angiotensin system can cause hyperkalemia, particularly in patients with renal insufficiency, diabetes, or combination use with other angiotensin receptor blockers or ACE inhibitors and the concomitant use of other drugs that raise serum potassium levels. Hydrochlorothiazide can cause hypokalemia and hyponatremia. May also cause hypomagnesemia resulting in hypokalemia. Monitor serum electrolytes periodically. Decreases urinary calcium excretion and may cause elevations of serum calcium. May alter glucose tolerance and raise serum levels of cholesterol and triglycerides. ***Hypersensitivity Reaction :*** May occur in patients with or without a history of allergy or bronchial asthma, but are more likely in patients with such a history. ***Acute Myopia and Secondary Angle-Closure Glaucoma :*** Hydrochlorothiazide can cause an idiosyncratic reaction, resulting in acute transient myopia, choroidal effusion and acute angle-closure glaucoma. ***Systemic Lupus Erythematosus*** : Thiazide diuretics have been reported to cause exacerbation or activation of systemic lupus erythematosus. ***Postsympathectomy Patients :*** The antihypertensive effects of hydrochlorothiazide may be enhanced in the postsympathectomy patient.
Pregnancy & Lactation: When pregnancy is detected, discontinue Telsite H as soon as possible. Because of the potential for serious adverse reactions in the breastfed infant advise nursing woman not to breastfeed during treatment with Telsite H. .
Adverse reactions: The most common adverse effects (≥2% of patients) were upper respiratory tract infection, dizziness, sinusitis, diarrhea, fatigue, influenza like symptoms and nausea.

For full prescribing information please write to: Sanofi India Limited, Sanofi house, C.T.S No-117-B, L& T Bussiness Park, Saki Vihar Road, Powai, Mumbai 400 072- India

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Source:

- Micardis HCT leaflet (Boehringer Ingelheim Pharmaceuticals) revised in August 2020 (accessed on 20th December 2020)
- For Hydrochlorothiazide : Source: CCDS Version18 dated 24 September 2020