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

Abridged Prescribing Information

Telmisartan, Hydrochlorothiazide & Amlodipine Tablets
Telsite® AMH

COMPOSITION : Each uncoated bilayered tablet contains Telmisartan IP 40mg + Hydrochlorothiazide IP 12.5mg + Amlodipine besylate IP equivalent to Amlodipine 5mg,

THERAPEUTIC INDICATIONS
For the treatment of essential hypertension. This fixed dose combination is not indicated for initial therapy.

DOSAGE AND ADMINISTRATION
One tablet once daily. Safety and effectiveness in paediatric patients has not been established. Dose selection for elderly patients should be cautious. Not recommended in severe renal impairment. Telsite AMH is not recommended in hepatically impaired patients.

SAFETY-RELATED INFORMATION
Contraindications: Patients with known hypersensitivity to any component, in patients with anuria. Do not co-administer with aliskiren in patients with diabetes.
Warnings and Precautions: Fetal toxicity - Use of drugs that act on the RAS during 2nd and 3rd trimesters reduces fetal renal function and increases fetal and neonatal morbidity and death. When pregnancy is detected, discontinue Telsite AMH as soon as possible. **Hypotension** - Symptomatic hypotension may occur after initialization of treatment with Telsite AMH. Correct volume or salt depletion prior to administration of Telsite AMH. **Impaired Renal Function** - Monitor renal function periodically. Consider withholding or discontinuing therapy in patients who develop a clinically significant decrease in renal function on Telsite AMH. **Hepatic Failure** : Telsite AMH is not recommended in hepatically impaired patients. **Dual Blockade of the Renin-Angiotensin-Aldosterone System and Changes in Renal Function** - Closely monitor blood pressure, renal function and electrolytes in patients on Telsite AMH and other agents that affect the RAS. Do not co-administer aliskiren with Telsite AMH in patients with diabetes and in patients with renal impairment. **Electrolytes and Metabolic Disorders** : 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. Thiazides have been shown to increase the urinary excretion of magnesium. Hydrochlorothiazide decreases urinary calcium excretion and may cause elevations of serum calcium. Hydrochlorothiazide may alter glucose tolerance and raise serum levels of cholesterol and triglycerides. Hyperuricemia may occur or frank gout may be precipitated in certain patients receiving thiazide therapy. **Hypersensitivity Reaction** : Hypersensitivity reactions to hydrochlorothiazide 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 and acute angle-closure glaucoma. The primary treatment is to discontinue. Prompt medical or surgical treatments may need to be considered if the intraocular pressure remains uncontrolled. **Systemic Lupus Erythematosus** : May cause exacerbation or activation of SLE. **Postsympathectomy Patients** : The antihypertensive effects of hydrochlorothiazide may be enhanced in the postsympathectomy patient. Increased Angina or Myocardial Infarction - Worsening angina and acute myocardial infarction can develop particularly in patients with severe obstructive coronary artery disease. **Heart Failure** : Closely monitor patients with heart failure.
Pregnancy & Lactation: Discontinue Telsite® AM H in pregnancy. Do not breastfeed during treatment with Telsite AMH.
Adverse Reactions: Common adverse effects: Fatigue, influenza like symptoms, dizziness, nausea, diarrhea, sinusitis and upper respiratory tract infection. Most common adverse reaction to amlodipine is oedema. Other adverse experiences not dose related but reported with an incidence >1.0% are fatigue, nausea, abdominal pain and somnolence.

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

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Source:

- Micardis® HCT (Boehringer Ingelheim Pharmaceuticals) US PI dated February 2018 accessed in June 2018
- Twynsta Leaflet (Boehringer Ingelheim Pharmaceuticals) dated February 2018 accessed on 6th June 2018
- Norvasc® (Pfizer) US PI dated October 2017 accessed in June 2018