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

Abridged Prescribing Information

Telmisartan Tablets I.P.
TELSITE ®

COMPOSITION: Telsite® 20mg/40mg/80mg: Each uncoated tablet contains: Telmisartan IP. 20 mg/ 40mg/ 8mg
THERAPEUTIC INDICATIONS: Treatment of hypertension; For the prevention of cardiovascular morbidity and mortality in patient 55 years older at high risk of cardiovascular disease.

DOSAGE & ADMINISTRATION: The usually effective dose is 40 mg once daily for treatment of hypertension. Some patients may already benefit at a daily dose of 20 mg. The recommended dose is 80 mg once daily for cardiovascular protection. **Pediatric patients** : Safety and efficacy not established in children and adolescents aged below 18 years. **Elderly patients** : No dose adjustment is necessary. **Hepatic impairment** : Contraindicated in severe hepatic impairment. In patients with mild to moderate hepatic impairment the posology should not exceed 40 mg once daily. **Renal impairment :** A lower starting dose of 20 mg is recommended in severe renal impairment or hemodialysis.

CONTRAINDICATIONS : Hypersensitivity to the active substance or to any of the excipients; 2nd or 3rd trimester of pregnancy; Biliary obstructive disorders; Severe hepatic impairment. Telmisartan with aliskiren is contraindicated in patients with renal impairment.

WARNINGS & PRECAUTIONS : *Pregnancy:* Angiotensin II receptor antagonists (AIIRAs) should not be initiated during pregnancy. *Hepatic impairment:* Telmisartan is not to be given to patients with cholestasis, biliary obstructive disorders or severe hepatic impairment. *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 with telmisartan. *Renal impairment and kidney transplantation:* Periodic monitoring of potassium and creatinine serum levels is recommended. *Intravascular hypovolemia :* Symptomatic hypotension, especially after the first dose of telmisartan, may occur. *Dual blockade of the renin-angiotensin-aldosterone system:* Combination with aliskiren is contraindicated. *Other conditions with stimulation of the renin-angiotensin-aldosterone system :* Telmisartan has been associated with acute hypotension, hyperazotaemia, oliguria, or rarely acute renal failure. *Primary aldosteronism:* Not recommended. *Aortic and mitral valve stenosis, obstructive hypertrophic cardiomyopathy:* Special caution is indicated. *Diabetic patients treated with insulin or antidiabetics :* Hypoglycemia may occur therefore appropriate blood glucose monitoring should be considered; a dose adjustment of insulin or antidiabetics may be required, when indicated. *Hyperkalemia :* The use of medicinal products that affect the renin-angiotensin-aldosterone system may cause hyperkalemia. In the elderly, in patients with renal insufficiency, in diabetic patients, in patients concomitantly treated with other medicinal products that may increase potassium levels, and/or in patients with intercurrent events, hyperkalemia may be fatal. *Ethnic differences*
Telmisartan is apparently less effective in lowering blood pressure in black people than in non-blacks, possibly because of higher prevalence of low-renin states in the black hypertensive population. *Other:* Excessive reduction of blood pressure in patients with ischemic cardiopathy or ischemic cardiovascular disease could result in a myocardial infarction or stroke.
INTERACTIONS : Contraindicated : Combination of telmisartan with aliskiren; co-administration with digoxin.
PREGNANCY : The use of AIIRAs is not recommended during the first trimester of pregnancy. The use of AIIRAs is contraindicated during the second and third trimesters of pregnancy.
LACTATION : Telmisartan is not recommended and alternative treatments with better established safety profiles during breast-feeding are preferable, especially while nursing a newborn or preterm infant.
ADVERSE REACTIONS : Serious adverse drug reactions include anaphylactic reaction and angioedema which may occur rarely (≥1/10,000 to <1/1,000), and acute renal failure. The overall incidence of adverse reactions reported with telmisartan was usually comparable to placebo.

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

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