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

Abridged Prescribing Information

TELSITE ®
Telmisartan Tablets IP

COMPOSITION
Telsite® 20mg / 40mg / 80mg: Each uncoated tablet contains Telmisartan IP 20 mg / 40 mg / 80 mg.

THERAPEUTIC INDICATIONS
Treatment of hypertension.

DOSAGE AND ADMINISTRATION
The usual starting dose of Telsite is 40 mg once a day. Blood pressure response is dose-related over the range of 20-80mg. Telsite may be administered with or without food.

SAFETY RELATED INFORMATION
Contraindications : In patients with known hypersensitivity (e.g., anaphylaxis or angioedema) to telmisartan or any other component of this product. Do not co-administer aliskiren with Telsite in patients with diabetes.
Warnings And Precautions : Use of drugs that act on the renin-angiotensin system during the second and third trimesters of pregnancy reduces fetal renal function and increases fetal and neonatal morbidity ,~~and~~ death. and injury to the developing fetus. In patients with an activated renin-angiotensin system, such as volume- or salt-depleted patients (e.g., those being treated with high doses of diuretics), symptomatic hypotension may occur after initiation of therapy with telmisartan. Either correct this condition prior to administration of telmisartan or start treatment under medical supervision with reduced dose. Hyperkalemia may occur in patients on ARBs (angiotensin-renin blockers), particularly in patients with advanced renal impairment, heart failure, on renal replacement therapy, or on potassium supplements, potassium-sparing diuretics, potassium-containing salt substitutes or other drugs that increase potassium levels. As the majority of telmisartan is eliminated by biliary excretion, patients with biliary obstructive disorders or hepatic insufficiency can be expected to have reduced clearance - initiate telmisartan at low dose and titrate slowly. Changes in renal function can be anticipated in susceptible individuals.
Dual blockade of the renin angiotensisn aldosterone system (RAS) with angiotensin-receptor blockers, ACE inhibitors, or aliskiren is associated with increased risks of hypotension, hyperkalemia, and changes in renal function (including acute renal failure) compared to monotherapy. Do not co-administer aliskiren with telmisartan in patients with diabetes. Avoid concomitant use of aliskiren with telmisartan in patients with renal impairment (GFR <60 mL/min/1.73 m^2). When pregnancy is detected, discontinue MICARDIS as soon as possible.
Pregnancy & Lactation: Telmisartan can cause fetal harm when administered to a pregnant woman. Use of drugs that act on the RAS in the second and third trimesters of pregnancy can result in oligohydramnios, reduced fetal renal function leading to anuria and renal failure, fetal lung hypoplasia, skeletal deformations, including skull hypoplasia, hypotension, and death. There is no information regarding the presence of telmisartan in human milk, the effects on the breastfed infant, or the effects on milk production. Because of the potential for serious adverse reactions in the breastfed infant including hypotension, hyperkalemia and renal impairment, advise a nursing woman not to breastfeed during treatment with telmisartan.
Adverse reactions: Renal dysfunction upon use with ramipril. The most common adverse events (≥1%) reported in hypertension trials are back pain, sinusitis, and diarrhea.

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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