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

Abridged Prescribing Information

TELSITE® am
Telmisartan & Amlodipine Tablets IP

COMPOSITION: Each uncoated tablet contains Telmisartan IP 40mg + Amlodipine Besilate IP equivalent to Amlodipine 5mg.

THERAPEUTIC INDICATIONS
For the treatment of essential hypertension.

DOSAGE AND ADMINISTRATION
Substitute Telsite am for its individually titrated components for patients on amlodipine and telmisartan. Telsite am may also be given with increased amounts of amlodipine, telmisartan, or both, as needed. Use Telsite am tablets to provide additional blood pressure lowering for patients not adequately controlled with amlodipine (or another dihydropyridine calcium channel blocker) alone or with telmisartan (or another angiotensin receptor blocker) alone. Dosage may be increased after at least 2 weeks to a maximum dose of 80/10 mg once daily, usually by increasing one component at a time but both components can be raised to achieve more rapid control. Majority of antihypertensive effect is attained within 2 weeks.• Initiate with 40/5 mg once daily. Switch patients who experience dose-limiting adverse reactions on amlodipine to Telsite am tablets containing a lower dose of that component.

SAFETY RELATED INFORMATION
Contraindications : In patients with known hypersensitivity (e.g., anaphylaxis or angioedema) to telmisartan, amlodipine or any other component of this product.
Warning and Precautions: Avoid foetal or neonatal exposure. Hypotension: Correct any volume or salt depletion before initiating therapy. Observe for signs and symptoms of hypotension. Symptomatic hypotension is possible, particularly in patients with severe aortic stenosis. 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, potassiumsparing diuretics, potassium-containing salt substitutes or other drugs that increase potassium levels. Consider periodic determinations of serum electrolytes to detect possible electrolyte imbalances, particularly in patients at risk. Titrate slowly in patients with hepatic or severe renal impairment. Dual blockade of the renin angiotensin aldosterone system with angiotensinreceptor 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 administer aliskiren with Telsite am in patients with diabetes or in patients with renal impairment. Worsening angina and acute myocardial infarction can develop after starting or increasing the dose of Telsite am, particularly in patients with severe obstructive coronary artery disease. Heart failure: Monitor for worsening.
Pregnancy & Lactation: When pregnancy is detected, discontinue Telsite am as soon as possible. Telsite am can cause foetal harm when administered to pregnant woman. 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. 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 Telsite am.
Adverse reactions: In the placebo-controlled factorial design study, the most common reasons for discontinuation of therapy with Telsite am tablets were peripheral edema, dizziness, and hypotension, each leading to discontinuation of ≤0.5% of Telstie am-treated patients. Adverse reactions that occurred at a ≥2% higher incidence on Telsite am tablets than placebo were peripheral edema (4.8% vs 0%), dizziness (3.0% vs 2.2%), and back pain (2.2% vs 0%).

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

Created: July 2019
Source: Twynsta leaflet (Boehringer Ingelheim Pharmaceuticals) dated July 2019 (accessed on24th March 2021).