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

Abridged Prescribing Information

Telmisartan & Amlodipine Tablets IP
TELSITE® am

Composition: Each uncoated tablet contains:Telmisartan IP 40 mg + Amlodipine Besilate I.P. equivalent to Amlodipine...5 mg. Excipients q.s. Colour: Ferric oxide Red USP-NF
Indications: For the treatment of essential hypertension.
Posology and Method of Administration: Patients receiving amlodipine and telmisartan from separate tablets can instead receive tablets of telmisartan/ amlodipine containing the same component doses. Patients should use the strength corresponding to their previous treatment. The recommended dose is 1 tablet of telmisartan/ amlodipine daily. The maximum daily dose of telmisartan is 80 mg and the maximum daily dose of amlodipine is 10 mg.
Special Populations: *Pediatric patients* : Safety and efficacy of telmisartan/ amlodipine in children aged below 18 years have not been established. *Elderly patients*: No dose adjustment is necessary for elderly patients. Caution is required when increasing the dosage. *Hepatic impairment*: For telmisartan, the posology should not exceed 40 mg once daily. Telmisartan/ amlodipine is contraindicated in patients with severe hepatic impairment. Should be administered with caution in patients with mild to moderate hepatic impairment. *Renal impairment* : No posology adjustment is required for patients with mild to moderate renal impairment. Limited experience is available in patients with severe renal impairment or haemodialysis. Caution is advised when using telmisartan/ amlodipine in such patients as amlodipine and telmisartan are not dialysable.
Contraindications : Hypersensitivity to the active substances, to dihydropyridine derivatives, or to any of the excipients, second and third trimesters of pregnancy, biliary obstructive disorders, severe hepatic impairment, severe hypotension, shock (including cardiogenic shock), obstruction of the outflow tract of the left ventricle (e.g. high grade aortic stenosis), hemodynamically unstable heart failure after acute myocardial infarction, concomitant use of telmisartan/ amlodipine with aliskiren-containing products is contraindicated in patients with diabetes mellitus or renal impairment (GFR < 60 ml/min/1.73 m2).
Special warnings and precautions for use: **Telmisartan :** *Pregnancy :* Should not be initiated during pregnancy. When pregnancy is diagnosed, treatment with angiotensin II receptor antagonists should be stopped immediately, and, if appropriate, alternative therapy should be started. *Hepatic impairment :* 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. *Renal impairment and kidney transplantation :* Periodic monitoring of potassium and creatinine serum levels is recommended. No experience in treating patients with recent kidney transplantation. *Intravascular hypovolaemia* : Symptomatic hypotension may occur. *Dual blockade of the renin-angiotensin-aldosterone system (RAAS):* Dual blockade of RAAS through the combined use of ACE-inhibitors, angiotensin II receptor blockers or aliskiren is not recommended. *Other conditions with stimulation of the renin-angiotensin-aldosterone system :* Treatment with medicinal products that affect this system, 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 in patients suffering from aortic or mitral stenosis, or obstructive hypertrophic cardiomyopathy. *Diabetic patients treated with insulin or antidiabetics :* Hypoglycaemia may occur. *Hyperkalaemia* : The use of medicinal products that affect the renin-angiotensin-aldosterone system may cause hyperkalaemia. Before considering the concomitant use, benefit risk ratio should be evaluated. *Intestinal angioedema*: Intestinal angioedema has been reported in patients treated with angiotensin II receptor antagonists. *Ethnic differences:* Telmisartan is apparently less effective in lowering blood pressure in black patients than in non-blacks. *Other:* Excessive reduction of blood pressure in patients with ischemic cardiopathy or ischemic cardiovascular disease could result in a myocardial infarction or stroke.
Amlodipine : The safety and efficacy of amlodipine in hypertensive crisis has not been established. *Cardiac failure :* Calcium channel blockers, should be used with caution in patients with congestive heart failure, as they may increase the risk of future cardiovascular events and mortality. *Hepatic impairment :* Amlodipine should be initiated at the lower end of the dosing range and caution should be used. *Elderly :* Increase of the dosage should take place with care. *Renal impairment :* Amlodipine may be used in such patients at normal doses. Changes in amlodipine plasma concentrations are not correlated with degree of renal impairment. Amlodipine is not dialysable.
Pregnancy: Not recommended during the 1st trimester, contraindicated during the 2nd and 3rd trimesters of pregnancy
Lactation: Not recommended and alternative treatments with better established safety profiles during breastfeeding are preferable, especially while nursing a newborn or preterm infant.
Undesirable effects: The most common reported adverse reaction are somnolence, dizziness, headache, palpitations, flushing, visual disturbances, abdominal pain, nausea, ankle swelling, oedema and fatigue. Serious adverse drug reactions include anaphylactic reaction and angioedema which may occur rarely (≥ 1/10,000 to < 1/1,000), and acute renal failure.

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

Reference: Amlodipine Besilate +Telmisartan Tablet CCDS Version 4 dated 12 Dec 2024
Updated: Feb 2025