

TELDAY AM

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

Abbreviated Prescribing information for TELDAY AM (Telmisartan 80mg and Amlodipine 5mg Tablets) [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Telmisartan blocks the vasoconstrictor and aldosterone-secreting effects of angiotensin-II by selectively blocking the binding of angiotensin-II to the AT1 receptor in many tissues, such as vascular smooth muscle and the adrenal gland and amlodipine is a long acting dihydropyridine calcium channel-blocking agent. Amlodipine inhibits the transmembrane influx of calcium ions into vascular smooth muscle and cardiac muscle. **INDICATION:** For the treatment of essential hypertension in adults. **DOSAGE AND ADMINISTRATION:** Should be administered once daily with or without food. It may be administered with other antihypertensive agents. **CONTRAINDICATION:** Prior hypersensitivity to telmisartan, amlodipine or other Calcium channel blockers or any component of this formulation. Patients with anuria, hereditary or idiopathic angioedema, pregnant and lactating females. **WARNINGS & PRECAUTIONS:** When pregnancy is detected, Telmisartan should be discontinued as soon as possible. The use of drugs that act directly on the renin angiotensin system during the second and third trimesters of pregnancy has been associated with fetal and neonatal injury, including hypotension, neonatal skull hypoplasia, symptomatic hypotension, anuria, reversible or irreversible renal failure, and death. Oligohydramnios has also been reported, presumably resulting from decreased fetal renal function, oligohydramnios in this setting has been associated with fetal limb contractures, craniofacial deformation, and hypoplastic lung development. Caution should be exercise in patients with biliary obstructive disorders or hepatic insufficiency. Impaired Renal Function, dual blockade of the 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. Caution should be exercised while administering amlodipine with any other peripheral vasodilator particularly in patients with severe aortic stenosis. **DRUG INTERACTIONS: Telmisartan:** Digoxin, warfarin, lithium and ramipril. **ADVERSE REACTIONS: Telmisartan:** Impotence, increased sweating, flushing, allergy, fever, leg pain, malaise, palpitation, angina pectoris, tachycardia, leg edema, abnormal ECG, insomnia, somnolence, migraine, vertigo, paresthesia, involuntary muscle contractions, hypoaesthesia, flatulence, constipation, gastritis, vomiting, dry mouth, hemorrhoids, gastroenteritis, enteritis, gastroesophageal reflux, toothache, non-specific gastrointestinal disorders, gout, hypercholesterolemia, diabetes mellitus, arthritis, arthralgia, leg cramps, anxiety, depression, nervousness, asthma, bronchitis, rhinitis, dyspnea, epistaxis, dermatitis, rash, eczema, pruritus, micturition frequency, cystitis, cerebrovascular disorders abnormal vision, conjunctivitis, tinnitus and ear ache. **Amlodipine:** Headache, peripheral oedema, fatigue, dizziness, flushing, palpitations, arrhythmia (including ventricular tachycardia and atrial fibrillation), bradycardia, chest pain, hypotension, peripheral ischemia, syncope, tachycardia, dizziness, postural hypotension, vasculitis, pancreatitis, vomiting, gingival hyperplasia, change of bowel habit, sexual dysfunction, nervousness, abnormal dreams, depersonalization, mood change; hyperglycemia, thirst, leukopenia, purpura, and thrombocytopenia

MARKETED BY:



TORRENT PHARMACEUTICALS LTD.

Torrent House, Off Ashram Road,

Ahmedabad-380 009, INDIA

IN/TELDEY AM 80,5mg/Aug-2015/01/AbPI

(Additional information is available on request)