

Telmilock™ AM

Telmisartan & Amlodipine

COMPOSITION

Telmilock™ AM 5/40: Each tablet contains Telmisartan Ph. Eur. 40 mg & Amlodipine Besilate Ph. Eur. equivalent to Amlodipine 5 mg.

Telmilock™ AM 5/80: Each tablet contains Telmisartan Ph. Eur. 80 mg & Amlodipine Besilate Ph. Eur. equivalent to Amlodipine 5 mg.

PHARMACOLOGY

Telmilock™ AM is a fixed dose combination of Amlodipine & Telmisartan. Amlodipine is a dihydropyridine calcium-channel blocker (CCB) that inhibits the transmembrane influx of calcium ion into vascular smooth muscle and cardiac muscle. Amlodipine is a peripheral arterial vasodilator that acts directly on vascular smooth muscle to cause a reduction in peripheral vascular resistance and reduction in blood pressure. Telmisartan blocks the binding of Angiotensin II to the AT₁ receptor in many tissues like vascular smooth muscle and the adrenal gland. Therefore, Telmisartan dilates blood vessels and reduces blood pressure without affecting pulse rate. Telmisartan has much greater affinity (>3,000 fold) for the AT₁ receptor than for the AT₂ receptor.

INDICATIONS

Hypertension.

DOSAGE & ADMINISTRATION

Initial Therapy: The usual starting dose of Amlodipine & Telmisartan 5/40 mg (**Telmilock™ AM 5/40**) is once daily. Patients requiring larger blood pressure reductions may be started with 5/80 mg (**Telmilock™ AM 5/80**) once daily.

Add-on Therapy: Patients not adequately controlled with Amlodipine alone or with Telmisartan. Patients treated with 10 mg Amlodipine who experience adverse reactions such as edema, may be switched to **Telmilock™ AM 5/40** tablet once daily, reducing the dose of Amlodipine without reducing the overall expected antihypertensive response.

Replacement Therapy: Patients receiving Amlodipine and Telmisartan from separate tablets may instead receive **Telmilock™ AM** tablet containing the same component doses once daily.

Dosage must be individualized and may be increased after at least 2 weeks. The maximum recommended dose of Telmisartan & Amlodipine tablet is 80/10 mg once daily.

Children & Adolescent Dose: The safety and efficacy of Telmisartan & Amlodipine combination in children aged below 18 years have not been established.

SIDE EFFECTS

Dizziness, peripheral edema, migraine, headache, paraesthesia, vertigo, bradycardia, palpitation, hypotension, cough, abdominal pain, diarrhea, nausea, pruritus, myalgia, spasm, fatigue, etc.

CONTRAINDICATIONS

Known hypersensitivity to this product or any of its components. Pregnancy & lactation, biliary obstructive disorders, severe hepatic impairment, hypotension & cardiogenic shock.

WARNINGS & PRECAUTIONS

- Avoid fetal or neonatal exposure
- Hypotension: Correct any volume or salt depletion before initiating therapy. Observe for signs and symptoms of hypotension.
- Titrate slowly in patients with hepatic or severe renal impairment

- Heart failure: Monitor for worsening
- Avoid concomitant use of an ACE inhibitor and angiotensin receptor blocker
- Myocardial infarction: Uncommonly, initiating a CCB in patients with severe obstructive coronary artery disease may precipitate myocardial infarction or increased angina

OVERDOSE

Telmisartan: Overdose may cause hypotension, dizziness, and tachycardia; bradycardia could occur from parasympathetic (vagal) stimulation.

Amlodipine: Overdose may cause excessive peripheral vasodilation with marked hypotension and possibly reflex tachycardia. If massive overdose occur, active cardiac and respiratory monitoring should be instituted. Frequent blood pressure measurements are essential.

USE IN SPECIFIC POPULATION

Pregnancy: Pregnancy Categories C (first trimester) and D (second and third trimesters).

Lactation: It is not known whether Amlodipine & Telmisartan is excreted in human milk.

Geriatric use: Initial therapy with Amlodipine & Telmisartan combination tablet is not recommended in patients 75 years of age and older.

Hepatic impairment: Initial therapy with Amlodipine & Telmisartan combination is not recommended in hepatic impaired patients.

DRUG INTERACTION

Co-administration of Telmisartan did not result in a clinically significant interaction with Acetaminophen, Amlodipine, Glyburide, Hydrochlorothiazide, Warfarin, or Ibuprofen. Telmisartan is not metabolized by the cytochrome P450 system and had no effects in vitro on cytochrome P450 enzymes, except for some inhibition of CYP2C19. Telmisartan is not expected to interact with drugs that inhibit or are metabolized by cytochrome P450 enzymes, except for possible inhibition of the metabolism of drugs metabolized by CYP2C19. In clinical trials, Amlodipine has been safely administered with thiazide diuretics, beta-blockers, angiotensin-converting enzyme inhibitors, long-acting nitrates, sublingual nitroglycerin, digoxin, warfarin, non-steroidal anti-inflammatory drugs, antibiotics, and oral hypoglycemic drugs.

STORAGE

Store below 30° C, protect from light & moisture. Keep out of the reach of children.

HOW SUPPLIED

Telmilock™ AM 5/40: Each box contains 30 tablets in blister pack.

Telmilock™ AM 5/80: Each box contains 30 tablets in blister pack.

Manufactured by



SQUARE
PHARMACEUTICALS PLC.
BANGLADESH