

# Camlotel™

## Amlodipine & Telmisartan

### PRESENTATION

**Camlotel™ 5/40:** Each tablet contains Amlodipine Besilate BP equivalent to Amlodipine 5 mg & Telmisartan EP 40 mg.

### PHARMACOLOGY

**Camlotel™** 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 Angiotensin II by selectively blocking the binding of Angiotensin II to the AT<sub>1</sub> 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 AT<sub>1</sub> receptor than for the AT<sub>2</sub> receptor.

### INDICATIONS

Treatment of hypertension, alone or with other antihypertensive agents. It may also be used as initial therapy in patients who are likely to need multiple drugs to achieve their blood pressure goals.

### DOSAGE & ADMINISTRATION

**Initial Therapy:** The usual starting dose of Amlodipine & Telmisartan is 5/40 mg (Camlotel™ 5/40) once daily. Patients requiring larger blood pressure reductions may be started with 5/80 mg 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 **Camlotel™ 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 **Camlotel™** 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 Amlodipine & Telmisartan tablet is 10/80 mg once daily.

### SIDE EFFECTS

Dizziness, peripheral edema, migraine, headache, paraesthesia, vertigo, bradycardia, palpitations, 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, hypertension & cardiogenic shock.

### WARNINGS

- 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

### 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. Because of the potential for adverse effects on the nursing infant, discontinue nursing or discontinue the drug after taking into account the importance of the drug to the mother.

**Pediatric use:** Safety and effectiveness of Amlodipine & Telmisartan combination in pediatric patients have not been established.

**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

**Camlotel™ 5/40:** Each box contains 30 tablets in blister pack.

Manufactured by



**SQUARE**

**PHARMACEUTICALS LTD.**  
**BANGLADESH**