Temcard-A

Telmisartan & Amlodipine Tablet

PRESENTATION

Temcard-A 40/5 Tablet: Each tablet contains Telmisartan USP 40 mg and Amlodipine Besilate BP equivalent to Amlodipine 5 mg.
Temcard-A 80/5 Tablet: Each tablet contains Telmisartan USP 80 mg and Amlodipine Besilate BP equivalent to Amlodipine 5 mg.

PHARMACOLOGY

Temcard-A is a fixed dose combination of Telmisartan and Amlodipine. Telmisartan blocks the vasoconstrictor and aldosterone-secreting effects of angiotensin II by selectively blocking the binding of angiotensin II to the AT_1 receptor in many tissues, such as vascular smooth muscle and the adrenal gland. Its action is therefore independent of the pathways for angiotensin II synthesis. Telmisartan has much greater affinity (>3,000 fold) for the AT_1 receptor than for the AT_2 receptor. Because Telmisartan does not inhibit ACE (kininase II), it does not affect the response to bradykinin. Telmisartan does not bind to or block other hormone receptors or ion channels known to be important in cardiovascular regulation.

Amlodipine, a dihydropyridine calcium-channel blocker (CCB), 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.

INDICATIONS

- **Temcard-A** is indicated for the treatment of hypertension, alone or with other antihypertensive agents to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular eve nts, primarily strokes and myocardial infarctions.
- **Temcard-A** is also indicated as initial therapy in patients likely to need multiple antihypertensive agents to achieve their blood pressure goals.

DOSAGE & ADMINISTRATION

Initial Therapy: Patient may be initiated on **Temcard-A** tablets if it is unlikely that control of blood pressure would be achieved with a single agent. The usual starting dose is 40/5 mg once daily. Patients requiring larger blood pressure reductions may be started with **Temcard-A 80/5** mg once daily. Initial therapy with **Temcard-A** is not recommended in patients >75 years old or with hepatic impairment.
Add-on Therapy: **Temcard-A** may be used 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. Patients treated with 10 mg amlodipine who experience adverse reactions such as edema, may be switched to **Temcard-A** 40/5 mg tablets 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 **Temcard-A** tablets 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 **Temcard-A** tablet is 80/10 mg once daily.

ADVERSE REACTIONS

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

CONTRAINDICATIONS

Telmisartan and amlodipine combination tablet is contraindicated in patients with known hypersensitivity to Telmisartan, amlodipine or any other component of this product.

WARNINGS AND PRECAUTIONS

Fetal toxicity: Use of Telmisartan increases fetal and neonatal morbidity and death. ***Hypotension:*** Symptomatic hypotension may occur after initiation of Telmisartan in patients treated with high dose of diuretics. Amlodipine may also cause symptomatic hypotension particularly in patients with severe aortic stenosis. ***Hyperkalemia:*** Hyperkalemia may occur in patients on ARBs, particularly in patients with advanced renal impairment, heart failure, on renal replacement therapy or on other drugs that increase potassium levels. ***Impaired hepatic function:*** As majority of Telmisartan is eliminated by biliary excretion, patients with biliary obstructive disorder or hepatic insufficiency can be expected to have reduced clearance. Initiate Telmisartan at low dose and titrates slowly in these patients. For patients with hepatic impairment, start Amlodipine or add Amlodipine at 2.5 mg as these patients have decreased clearance of Amlodipine. ***Impaired renal function:*** As Telmisartan inhibits renin-angiotensin-aldosterone system, changes in renal function in susceptible patients can be anticipated.

DRUG INTERACTION

Aliskerin: Avoid use of aliskerin with Telmisartan in patients with renal impairment (GFR<60 mL/min). ***Digoxin:*** When Telmisartan is co-administered with digoxin, increase in digoxin plasma concentration is observed. ***Lithium:*** Increase in serum lithium concentration is observed when lithium is co-administered with Telmisartan. ***NSAIDs:*** Antihypertensive effect of Telmisartan may be attenuated with NSAIDs. ***Simvastatin:*** Limit the dose of simvastatin in patients on Amlodipine to 20 mg daily. ***CYP3A4 inhibitors:*** Co-administration of diltiazem with amlodipine may result in increase in Amlodipine systemic exposure. ***CYP3A4 inducers:*** No information is available on the effects of CYP3A4 inducers (e.g: carbamazepine, phenobarbitol, phenytoin, rifampicin etc.) on Amlodipine.

USE IN SPECIFIC POPULATION

- ***Pregnancy:*** When pregnancy is detected, discontinue Telmisartan and Amlodipine combination as soon as possible.
- ***Lactation:*** It is not known whether Telmisartan and Amlodipine 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 Telmisartan and Amlodipine combination in pediatric patients have not been established.
- ***Geriatric use:*** No overall differences in effectiveness and safety were observed in these patients compared to younger patients.
- ***Hepatic impairment:*** Initial therapy with Telmisartan and Amlodipine combination is not recommended in hepatically impaired patients.
- ***Renal impairment:*** As Telmisartan inhibits renin-angiotensin-aldosterone system, changes in renal function in susceptible patients can be anticipated.

OVER DOSAGE

Telmisartan: Limited data are available with regard to over dosage in humans. The most likely manifestations of over dosage with Telmisartan tablets would be hypotension, dizziness, and tachycardia; bradycardia could occur from parasympathetic (vagal) stimulation. If symptomatic hypotension should occur, supportive treatment should be instituted. Telmisartan is not removed by hemodialysis. ***Amlodipine:*** Over dosage might be expected to 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. If hypotension occurs, cardiovascular support including elevation of the extremities and the judicious administration of fluids should be initiated. If hypotension remains unresponsive to these conservative measures, administration of vasopressors (such as phenylephrine) should be considered with attention to circulating volume and urine output. Amlodipine is not removed by hemodialysis.

STORAGE

Store below 25^0 C. keep in dry place & protect from light. Keep out of the reach of children.

P A C K I N G

Temcard-A 40/5 Tablet: Each box contains 30 tablets in Alu-Alu blister pack.
Temcard-A 80/5 Tablet: Each box contains 30 tablets in Alu-Alu blister pack.

Manufactured by:
ARISTOPHARMA LTD.
Shampur-Kadamtali I/A, Dhaka-Bangladesh

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Size: 127 mm x 400 mm