Teslar-M

Amlodipine & Telmisartan

COMPOSITION

Teslar-M 5/40 Tablet: Each film coated tablet contains Amlodipine Besilate BP equivalent to Amlodipine 5 mg and Telmisartan USP 40 mg.
Teslar-M 5/80 Tablet: Each film coated tablet contains Amlodipine Besilate BP equivalent to Amlodipine 5 mg and Telmisartan USP 80 mg.

DESCRIPTION

Teslar-M is a combination of Telmisartan and Amlodipine where Telmisartan is a nonpeptide angiotensin II receptor blocker and Amlodipine is a dihydropyridine calcium channel blocker. 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. Amlodipine acts directly on vascular smooth muscle to cause a reduction in peripheral vascular resistance and reduction in blood pressure.

INDICATIONS

Teslar-M is indicated for the treatment of hypertension alone or with other antihypertensive agents. **Teslar-M** is indicated as initial therapy in patients likely to need multiple antihypertensive agents to achieve their blood pressure goals.

DOSAGES AND ADMINISTRATION

Route of administration: Oral route only.
Dosage: Treatment of hypertension: The usual recommended dosage of **Teslar-M** is one tablet once daily. Initiate with 5/40 mg, dosage may be increased after at least 2 weeks to a maximum dose of 5 / 80 mg once daily. A majority of antihypertensive effect is attained within 2 weeks.
Hepatic Insufficiency: Monitor carefully and titrate slowly in patients with biliary obstructive disorders or hepatic insufficiency. Since patients with hepatic impairment have decreased clearance of Amlodipine, start Amlodipine or add Amlodipine 2.5 mg to Telmisartan. The lowest dose is 5/40 mg; therefore, initial therapy with **Teslar-M** tablets is not recommended in hepatically impaired patients.

CONTRAINDICATIONS

- Known hypersensitivity (e.g., anaphylaxis or angioedema) to Telmisartan, Amlodipine or any other component of this product.
- Do not co-administer aliskiren in patients with diabetes.

WARNING AND 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.

SIDE EFFECTS

The most common side effects include dizziness, peripheral edema, drowsiness, tired feeling, flushing (warmth, redness or tingly feeling), back pain, nausea, Diarrhea, stomach pain. Swelling hands/ankles/feet or flushing may occur.

USE IN SPECIFIC POPULATION

Pregnancy: Pregnancy Categories C (first trimester) and D (second and third trimesters). When pregnancy is detected, discontinue this combination product 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 & Amlodipine combination in pediatric patients have not been established.
Geriatric use: Initial therapy with Telmisartan & Amlodipine combination is not recommended in patients ≥75 years old.

DRUG INTERACTIONS

With medicine: Co-administration of Telmisartan did not result in a clinically significant interaction with Acetaminophen, Amlodipine, Glyburide, Simvastatin, Hydrochlorothiazide, Warfarin, or Ibuprofen. The increased risk of renal impairment and loss of antihypertensive effect when administered with NSAIDs. If Simvastatin is co-administered with Amlodipine, doses should not be greater than 20 mg daily of Simvastatin. Amlodipine has no clinically relevant effects on the pharmacokinetics or pharmacodynamics of the following: Atorvastatin, Digoxin, and Warfarin.
With food & others: Bioavailability may be slightly reduced by taking telmisartan with food.

OVER DOSAGE

Telmisartan: Limited data are available with regard to overdose in humans. The most likely manifestation of overdose with Telmisartan would be hypotension, dizziness and tachycardia. If overdose occurs, supportive treatment should be given.
Amlodipine: Single oral doses of Amlodipine to 40 mg/kg and 100 mg/kg amlodipine in mice and rats, respectively, caused deaths. Single oral doses equivalent to 4 or more mg/kg amlodipine in dogs caused a marked peripheral vasodilation and hypotension.

STORAGE CONDITION

Store below 30°C and dry place, away from light. Keep out of the reach of children.

COMMERCIAL PACK

Teslar-M 5/40 Tablet: Each commercial box contains 28 film coated tablets in Alu-Alu blister pack.
Teslar-M 5/80 Tablet: Each commercial box contains 28 film coated tablets in Alu-Alu blister pack.

Manufactured By
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