

Telflink[®]-AM

(Telmisartan & Amlodipine Tablets)

Composition:

Each Uncoated Bilayered Tablet Contains:

Telmisartan IP..... 40mg
Amlodipine Besylate I.P.
Eui.to Amlodipine.....5mg
Exicipents...q.s.
Colour: Ponceau 4R

Clinical Pharmacology:

Telmisartan:

Angiotensin II is formed from angiotensin I in a reaction catalyzed by angiotensin-converting enzyme (ACE, kininase II). Angiotensin II is the principal pressor agent of the renin-angiotensin system, with effects that include vasoconstriction, stimulation of synthesis and release of aldosterone, cardiac stimulation, and renal reabsorption of sodium. 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. Its action is therefore independent of the pathways for angiotensin II synthesis.

Amlodipine:

Amlodipine is calcium channel blocker. Amlodipine Inhibits calcium ion influx across cell membranes, with a greater effect on vascular smooth muscle cells. This causes vasodilation and a reduction in peripheral vascular resistance, thus lowering blood pressure.

Indications:

In hypertensive with metabolic risk factors

Use in special population:

Renal Impairment: No initial dosage adjustment is required for patients with mild or moderate renal impairment. Titrate slowly in patients with severe renal impairment.

Hepatic Impairment: In most patients, initiate amlodipine therapy at 2.5 mg. Titrate slowly in patients with hepatic impairment.

Patients 75 Years of Age and Older: In most patients, initiate amlodipine therapy at 2.5 mg. Titrate slowly in patients 75 years of age and older.

Contraindications:

Known hypersensitivity (e.g., anaphylaxis or angioedema) to telmisartan or any other component of this product Known sensitivity to amlodipine.

Precautions and Warnings:

- Hypotension: Correct any volume or salt depletion before initiating therapy. Observe for signs and symptoms of hypotension
- Monitor carefully in patients with impaired hepatic or renal function
- Avoid concomitant use of an ACE inhibitor and angiotensin receptor blocker
- Titrate slowly when administering calcium channel blockers to patients with severe hepatic impairment.

Adverse effects:

- Hypertension: The most common adverse events ($\geq 1\%$) reported in hypertension trials are back pain, sinusitis, and diarrhea.
- Cardiovascular risk reduction: The serious adverse events ($\geq 1\%$) reported in cardiovascular risk reduction trials were intermittent claudication and skin ulcer.
- Most common adverse reactions are headache and edema which occurred in a dose related manner. Other adverse experiences not dose related but reported with an incidence $>1.0\%$ are headache, fatigue, nausea, abdominal pain, and somnolence.

Overdosage:

The overdosage with Telflink-AM tablets would be hypotension, dizziness and tachycardia; bradycardia could occur from parasympathetic (vagal) stimulation.

SCHEDULE H PRESCRIPTION DRUG-CAUTION Not to be sold by retail without Prescription of a Registered Medical Practitioner.

Keep all medicines out of reach of children.

For therapeutic use.

Route of administration: Oral.

Dosage: As directed by the physician

Storage: Store in cool, dry & dark place.

Presentation: Telflink-AM is available as 10x 10 Tablets.

Marketed By:



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