

(Telmisartan and Hydrochlorothiazide Tablets U.S.P.)

Composition:

Each Uncoated Tablet Contains:

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.

Hydrochlorothiazide:

It is a thiazide diuretic. Thiazides affect the renal tubular mechanisms of electrolyte reabsorption, directly increasing excretion of sodium salt and chloride in approximately equivalent amounts. Indirectly, the diuretic action of hydrochlorothiazide reduces plasma volume, with consequent increases in plasma renin activity, increases in aldosterone secretion, increases in urinary potassium loss, and decreases in serum potassium. The renin aldosterone link is mediated by angiotensin II, so coadministration of an angiotensin II receptor antagonist tends to reverse the potassium loss associated with these diuretics.

Telmisartan and hydrochlorothiazide which lowers the blood pressure effectively. Telmisartan is an Angiotensin receptor blocker (ARB). It works by blocking the hormone angiotensin, thereby relaxing the blood vessels. This allows the blood to flow more smoothly and the heart to pump more efficiently. Hydrochlorothiazide is a diuretic that removes extra water and certain electrolytes from the body. Over time it also relaxes blood vessels and improves blood flow.

Indications:

Treatment of hypertension when monotherapy is unable to control hypertension goal.

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 amlodipinetherapyat2.5mg. 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 Hydrochlorothiazide is contraindicated in all of the following conditions: Anuria, Hypersensitivity (should not be given to those with allergies to sulfonamidederived drugs)

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.

Adverseneffects:

- Hypertension: The most common adverse events (≥1%) reported in hypertension trials are back pain, sinusitis, and diarrhea.
- Cardiovascular risk eduction: The serious adverse events(≥1%)reported in cardiovascular risk reduction trials were intermittent claudication and skin ulcer.

Overdosage:

The Overdosage with Telflink-H 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.

WARNING: When pregnancy is detected. Telmisartan should be discontinued as soon as possible, it can cause injury and even death to the developing fetus, when used in pregnancy during second and third trimester of pregnancy.

For Therapeutic use.

Route of administration: Oral.

Dosage: As directed by the physician.

Storage: Store in cool, dry & dark place.

Presentation: Telflink-H is available as 10x10 Tablet.

Marketed By:



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