

TELMI TAB - 40 H**TELMI TAB - 80 H**

Telmisartan 40 mg and Hydrochlorothiazide 12.5 mg Tablets USP
Telmisartan 80 mg and Hydrochlorothiazide 12.5 mg Tablets USP

COMPOSITION:

TELMI TAB - 40 H: Each uncoated tablet contains: Telmisartan USP 40 mg
Hydrochlorothiazide USP 12.5mg

TELMI TAB - 80 H: Each uncoated tablet contains: Telmisartan USP 80 mg
Hydrochlorothiazide USP 12.5mg

PHARMACOLOGICAL ACTION: Telmi Tab 40 H / Telmi Tab 80 H is a fixed dose of combination of telmisartan, an orally active angiotensin II antagonist acting on the AT1 receptor subtype, and hydrochlorothiazide, a diuretic.

PHARMACOLOGY:

Telmisartan antagonizes the effect of angiotensin II (vasoconstriction and aldosterone secretion) by blocking the angiotensin II(AT receptor) in vascular smooth muscle and the adrenal gland, producing decreased BP.

Hydrochlorothiazide increases chloride, sodium, and water excretion by interfering with transport of sodium ions across renal tubular epithelium.

INDICATION: Telmi Tab 40 H / Telmi Tab 80 H is indicated for the treatment of hypertension. This fixed dose combination is not indicated for initial therapy.

DOSAGE AND METHOD OF ADMINISTRATION: The usual initial dosage is one tablet of Telmi Tab 40 H daily. A patient whose blood pressure is not adequately controlled with telmisartan monotherapy 40 mg may be switched to Telmi Tab H. The dose may be increased, if necessary, to two tablets of Telmi Tab 40 H or one tablet of Telmi Tab 80 H daily. Telmi Tab H may be administered with other antihypertensive agents. It may be administered with or without food. The combination may be substituted for the titrated components.

Patients with renal impairment: The usual regimens of therapy with Telmi Tab H may be followed as long as the patients creatinine clearance is > 30 mL/min. In patients with more severe renal impairment, Telmi Tab H is not recommended.

Patients with Hepatic impairment: Telmi Tab H is not recommended for patients with severe hepatic impairment. Patients with biliary obstructive disorders or hepatic insufficiency should have treatment started under close medical supervision.

CONTRAINDICATIONS:

Hypersensitivity to any component of this product, Hypersensitivity to other sulfonamide derived drugs.

UNDESIRABLE EFFECTS: The combination of telmisartan and hydrochlorothiazide is generally well tolerated. The most frequent clinical adverse effects in patients treated with this combination are fatigue, dizziness, diarrhoea, nausea, back pain, dyspepsia, vomiting, tachycardia, hypokalaemia, bronchitis, rash and postural hypotension.

OVERDOSAGE: Limited data are available with regard to overdosage in humans. If symptomatic hypotension occur, supportive treatment should be instituted. Telmisartan is not removed by haemodialysis. The degree to which hydrochlorothiazide is removed by haemodialysis has not been established.

PRESENTATION:

Alu-Alu Blister pack of 3 X 10 Tablets
Alu-Alu Blister pack of 1 X 10 Tablets

STORAGE INSTRUCTIONS:

Caution: Keep all medicines away from the reach of children.

Storage:

Store in a cool, dark & dry place at a temperature below 30°C.
Protected from moisture

Manufactured for:

SPLEF1186

**Galaxy Pharmaceuticals**

Regd. Off.: B No. 36, Gala No. 2,3,4A,
Bhiwandi, Thane (Mumbai) M.S. India.



Manufactured by:

FREDUN PHARMACEUTICALS LTD.

14, 15, 16, Zorabian Industrial Complex,
Vevoor, Palghar (E) - 401 404. INDIA

FREDUN PHARMACEUTICALS LTD.

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| BUYER & COUNTRY | GALAXY PHARMA - RWANDA | COLOUR SHADE | ■ C:0 M:0 Y:0 K:100 |
| BRAND | TELMI TAB 40 & 80 H | Paper & Grammage | 54 GSM |
| GENERIC | Telmisartan 40 mg and Hydrochlorothiazide 12.5 mg Tablets USP Telmisartan 80 mg and Hydrochlorothiazide 12.5 mg Tablets USP | PRODUCT CODE | SPLEF1186 |
| Lic. No. | KD-135 | Registration No. | NA |
| PACK SIZE | 3 X 10 TABLETS | NAME OF ARTIST | Rao :) |
| SIZE OF LEAFLET | 140 (L) X 180 (H) mm | APPROVED BY | |