Telmilok™ *Plus*

Telmisartan EP 40 mg & Hydrochlorothiazide EP 12.5 mg

COMPOSITION: Telmilok™ *Plus 40/12.5* Tablet: Each tablet contains Telmisartan EP 40 mg & Hydrochlorothiazide EP 12.5 mg.

PHARMACOLOGY: 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. Hydrochlorothiazide affects the renal tubular mechanisms of electrolyte reabsorption, increases excretion of sodium salt and chloride and thus reduces plasma volume.

INDICATION : Hypertension

DOSAGE & ADMINISTRATION: For hypertension the starting dose is 40/12.5 mg once daily and maximum dose is 160/25 mg once daily.

SIDE EFFECTS: Telmisartan- Upper respiratory tract infection, back pain, sinusitis, diarrhea, pharyngitis, influenza-like symptoms, myalgia, urinary tract infection, abdominal pain, headache, dizziness, fatigue, coughing, nausea, peripheral edema, increased sweating, malaise, palpitation, angina pectoris, tachycardia, abnormal ECG, insomnia, migraine, vertigo, hypoesthesia, flatulence. Hydrochlorothiazide-weakness, pancreatitis, jaundice, gastric irritation, aplastic anemia, agranulocytosis, hemolytic anemia, thrombocytopenia, purpura, photosensitivity, urticaria, fever, anaphylactic reactions, interstitial nephritis, transient blurred vision etc.

PRECAUTIONS: Hypotension: In some patients symptomatic hypotension may occur after initiation of therapy with this drug. Impaired Hepatic Function: Initiate Telmisartan at low doses and titrate slowly in these patients. Impaired Renal Function: Changes in renal function including acute renal failure can be caused by drugs that inhibit the renin-angiotensin system and by diuretics. Monitor renal function periodically in patients with renal artery stenosis, chronic kidney disease, severe congestive heart failur or volume depletion and consider withholding or discontinuing therapy who develop a clinically significant decrease in renal function on this drug. Electrolytes and Metabolic Disorders: Hydrochlorothiazide may cause elevations of serum calcium. Hydrochlorothiazide may alter glucose tolerance and raise serum levels of cholesterol and triglycerides.

CONTRAINDICATION: Aliskiren, ACE Inhibitors.

DRUG INTERACTION: Telmisartan: Agents increasing serum potassium: Co-administration of Telmisartan with other drugs that raise serum potassium levels may result in hyperkalemia. Digoxin: When co-administered with Digoxin, median increases in Digoxin peak plasma concentration were observed. Non-Steroidal Anti-Inflammatory Agents including Selective COX-2 Inhibitors: In patients who are elderly, volume-depleted (including those on diuretic therapy), or with compromised renal function, co-administration of NSAIDs, including selective COX-2 inhibitors, with angiotensin II receptor antagonists, including Telmisartan, may result in deterioration of renal function, including possible acute renal failure. These effects are usually reversible. Monitor renal function periodically in patients receiving Telmisartan and NSAID therapy. The antihypertensive effect of angiotensin II receptor antagonists, including Telmisartan may be attenuated by NSAIDs including selective COX-2 inhibitors. Hydrochlorothiazide: Administration of a non-steroidal anti-inflammatory agent, including a selective COX-2 inhibitor, can reduce the diuretic, natriuretic, and antihypertensive effects of diuretics.

USE IN PREGNANCY AND LACTATION: Pregnancy- Telmisartan can cause fetal harm when administered to a pregnant woman.
Hydrochlorothiazide- Thiazides cross the placenta, and use of thiazides during pregnancy is associated with a risk of fetal or neonatal jaundice, thrombocytopenia, and possible other adverse reactions that have occurred in adults.
Lactation- Limited published studies report that hydrochlorothiazide is present in human milk. There is no information regarding the presence of Telmisartan in human milk. Nursing woman should not breastfeed during treatment with Telmisartan.

STORAGE: Store below 30^0 C. Protect from light & moisture. Keep out of the reach of the children.

HOW SUPPLIED: Telmilok™ *Plus 40/12.5* Tablet: Each box contains 30 Tablets in blister pack.

Manufactured by

SQUARE
PHARMACEUTICALS LTD.
BANGLADESH