Telisa Plus

Tablet

Telmisartan USP & Hydrochlorothiazide BP

Composition
Telisa Plus 40/12.5 mg: Each tablet contains Telmisartan USP 40 mg and Hydrochlorothiazide BP 12.5.
Telisa Plus 80/12.5 mg: Each tablet contains Telmisartan USP 80 mg and Hydrochlorothiazide BP 12.5.

Pharmacology
Telmisartan: Telmisartan is an angiotensin-II receptor blocker. Angiotensin-II is a potent vasoconstrictor. The primary vasoactive hormone of the renin-angiotensin system and an important component in the pathophysiology of hypertension. The angiotensin-II receptor blockers block the vasoconstrictor and aldosterone secreting effects of the angiotensin-II by selectively blocking the binding of angiotensin-II. They have many properties and effects similar to those of the ACE inhibitors that they do not inhibit the breakdown of bradykinin and other kinins, thus they do not cause persistant dry cough as happens with ACE inhibitor.
Hydrochlorothiazide: Thiazides affect the renal tubular mechanism of electrolyte reabsorption, directly increasing excretion of sodium and chloride in approximately equivalent amounts. Indirectly, the diuretic action of hydrochlorothiazide reduces plasma volume, with consequent increases in plasma renin activity, increase in aldosterone secretion, increase in urinary potassium loss and decreases in serum potassium.

Pharmacokinetics
Telmisartan: Following oral administration, peak concentration (Cmax) of Telmisartan reached in 0.5 to 1 hour after dosing. Food slightly reduces the bioavailability of Telmisartan, with a reduction in the plasma concentration time curve (AUC) of about 6% with the 40 mg tablet and about 20% after a 160 mg dose. The absolute bioavailability of Telmisartan is dose dependent. At 40 mg and 160 mg the bioavailability was 42% and 58% respectively.
Hydrochlorothiazide: When plasma levels have been followed for at least 24 hours, the plasma half-life has been observed to vary between 5.6 to 14.8 hours.

Indications
This combined preparation is indicated for the treatment of hypertension. These fixed dose combinations are not indicated for initial therapy of hypertension.

Dosage and Administration
Route of administration: Oral
The usual starting dose of this combination preparation is Telmisartan 40 mg once daily; blood pressure response is dose related over the range 40-80 mg. Hydrochlorothiazide is effective in doses of 12.5 mg to 50 mg once daily and can be given at doses of 12.5 mg to 25 mg.
It is usually appropriate to begin combination therapy only after a patient has failed to achieve the desired effect with monotherapy. Telmisartan combination therapy may be administered with other antihypertensive drugs & it also may be administered with or without Food.

Geriatric Patients
No overall differences in efficacy or safety vs younger patients.

Contraindications
This combined preparation is contraindicated in patients with anuria or hypersensitivity to other sulfonamide derived drugs.

Warnings and Precautions
Impaired Hepatic function: As the majority, Telmisartan is eliminated by biliary excretion, patients with biliary obstructive disorders or hepatic insufficiency can expect to have reduced clearance. Telmisartan & Hydrochlorothiazide should be used with caution in these patients.
Impaired Renal function: As a consequence of inhibiting Rennin-Angiotensin-Aldosteron System, changes in renal function may be anticipated in susceptible individuals. Caution should be taken for these patients.

Side-effects
Common side effects : Most side effects are mild to moderate and transient in nature and do not require discontinuation of therapy. Common side effects are diarrhea, nausea, dizziness, cough & fatigue.
Rare side effects : Change in vision, anemia, low blood pressure, chest pain.

Use in Pregnancy & Lactation
Pregnancy: When pregnancy is detected, Telisa Plus should be discontinued as soon as possible.
Lactation: This drug should not be used in lactation.

Use in Children & Adolescent
Safety and effectiveness of Telmisartan + Hydrochlorothiazide combination in pediatric patients have not been established.

Drug interaction
With medicine: Digoxin level may be monitored when initiating, adjusting and discontinuing Telmisartan. Alcohol, barbiturates, antidiabetic drugs may interact with thiazide diuretics.
With food & others : There are no established drug-food interaction.

Over dosage
Telmisartan: Limited data are available with regard to over dosage in humans. The most likely manifestations of over dosage with Telmisartan tablets would be hypotension, dizziness, and tachycardia; bradycardia could occur from parasympathetic (vagal) stimulation. If symptomatic hypotension should occur, supportive treatment should be instituted. Telmisartan is not removed by hemodialysis.
Hydrochlorothiazide : The most common signs and symptoms observed are those caused by electrolyte depletion (hypokalemia, hypochloremia) and dehydration resulting from excessive diuresis. If digitalis has also been administered, hypokalemia may accentuate cardiac arrhythmias.

Storage
Store below 25^0 C temperature & dry place, protected from light.
De-blister the tablet just before use & do not keep it open for more time.
Keep out of the reach of children.

Packing
Telisa Plus 40/12.5: Each box contains 3 x 10 tablets in Alu-Alu blister.
Telisa Plus 80/12.5: Each box contains 3 x 10 tablets in Alu-Alu blister.

***Further information is available on request.**

Manufactured by:
The ACME Laboratories Ltd.
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For Health, Vigour and Happiness