Telisa

Tablet

Telmisartan USP

Composition
Telisa 40: Each tablet contains Telmisartan USP 40 mg.
Telisa 80: Each tablet contains Telmisartan USP 80 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. Its action is therefore independent of the pathways for angiotensin II synthesis. Telmisartan has much greater affinity (>3,000 fold) for the AT_1 receptor than for the AT_2 receptor. Because Telmisartan does not inhibit ACE (kinase II), it does not affect the response to bradykinin. Telmisartan does not bind to or block other hormone receptors or ion channels known to be important in cardiovascular regulation.

Indication
Telisa is indicated for the treatment of hypertension. It may be used alone or in combination with other antihypertensive agents. It is also indicated for reduction of the risk of myocardial infarction, stroke, or death from cardiovascular causes in patients 55 years of age or older at high risk of developing major cardiovascular events who are unable to take ACE inhibitors.

Dosage and Administration
Route of administration: Oral.
Recommended Starting Dose
Hypertension
Dosage must be individualized. The usual starting dose of Telisa tablets is 40 mg once a day. Blood pressure response is dose-related over the range of 20 to 80 mg. Most of the antihypertensive effect is apparent within 2 weeks and maximal reduction is generally attained after 4 weeks. When additional blood pressure reduction beyond that achieved with 80 mg Telisa is required, a diuretic may be added. No initial dosage adjustment is necessary for elderly patients or patients with renal impairment, including those on hemodialysis.
Cardiovascular Risk Reduction
The recommended dose of Telisa tablets is 80 mg once a day and can be administered with or without food. It is not known whether doses lower than 80 mg of Telmisartan are effective in reducing the risk of cardiovascular morbidity and mortality.
When initiating Telmisartan therapy for cardiovascular risk reduction, monitoring of blood pressure is recommended, and if appropriate, adjustment of medications that lower blood pressure may be necessary.
OR AS DIRECTED BY THE PHYSICIAN.

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

Hepatic Impairment
Monitor carefully and up titrate slowly in patients with biliary obstructive disorders or hepatic insufficiency

Contraindications
Known hypersensitivity to this product or any of its components.

Warning & Precaution
- Avoid fetal or neonatal exposure
- Hypotension
- Monitor carefully in patients with impaired hepatic or renal function
- Avoid concomitant use of an ACE inhibitor and angiotensin receptor blocker

Side Effects
Common side effects: In hypertensive patients: The most common side effects of Telmisartan tablets include sinus pain and congestion (sinusitis), back pain, diarrhea etc.
For patients of cardiovascular risk reduction: The most common side effects of Telmisartan tablets in CV risk reduction include intermittent claudication and skin ulcer.
Rare side effects: Change in vision, anemia, low blood pressure, chest pain.

Use In Pregnancy & Lactation
Pregnancy: Telmisartan has been assigned to pregnancy category C (use during first trimester) & D (second and third trimester). When pregnancy is detected, Telmisartan should be discontinued as soon as possible.
Nursing Mothers: It is not known whether Telmisartan is excreted in human milk.

Use in Children & Adolescents
Safety and effectiveness of Telmisartan in pediatric patients have not been established.

Drug Interactions
With medicine: **Digoxin:** Co-administration of Telmisartan and Digoxin median increases in Digoxin peak plasma concentration (49%) and in trough concentration (20%) when observed. Therefore monitoring of Digoxin level is required when initiating, adjusting & discontinuing Telmisartan for the purpose of keeping the Digoxin level without the therapeutic range.
NSAIDS: Increased risk of renal impairment and loss of antihypertensive effect Co-administration with aliskiren with Telmisartan in patients with diabetes should be avoided.
Ramipril: When co-administering Telmisartan and Ramipril, the response may be greater because of the possibility of additive pharmacodynamics effects of the combined drugs. Concomitant use of Telmisartan and Ramipril is not recommended.
With food & others: There are no established drug-food interaction.

Overdose
The most likely manifestation of overdosage with Telmisartan tablets would be hypotension, dizziness and tachycardia; bradycardia, increase in serum creatinine and acute renal failure could occur from parasympathetic (vagal) stimulation.

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

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

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

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