Telmicard

Tablet

DRUG INTERNATIONAL LTD.

Composition : Telmicard : Each film coated tablet contains Telmisartan USP 40 mg.

Pharmacology : Telmisartan is an orally effective and specific angiotensin-II receptor (type AT) antagonist. Absorption of telmisartan is rapid and the mean bioavailability is about 50%. When it is administered with food, the reduction in the area under the plasma concentration-time curve (AUC) of telmisartan varies approximately 6% (40mg). There is no linear relation between doses and plasma level. Telmisartan is largely bound to plasma protein (>99.5). Telmisartan is nearly exclusively excreted with faeces mainly as unchanged compound. Cumulative urinary excretion is 1% of dose.

Indication : Telmisartan is indicated for the treatment of hypertension and cardiovascular (CV) risk reduction in patients unable to take ACE inhibitors.

Dosage and Administration :

Indication	Starting Dose	Dose Range
Hypertension	40 mg once daily	40 to 80 mg once daily
Cardiovascular Risk Reduction	80 mg once daily	80 mg once daily

Or, as directed by registered physician.

It may be administered with or without food.

Contraindicaion : It is contraindicated in patient having known hypersensitivity (e.g., anaphylaxis or angioedema) to telmisartan or any other component of this product and co-administration with aliskiren in patients with diabetes.

Precautions : Avoid fetal or neonatal exposure. 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.

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

Use in pregnancy & lactation : When pregnancy is diagonised telmisartan should be discontinued as soon as possible because it directly acts on the rennin-angiotensin system during second and third trimester associated with fetal and neonatal injury. It is contraindicated during lactation since it is not known whether it is excreted in human milk.

Use In Child : Safety and effectiveness of telmisartan in paediatric patient have not been established.

Drug Interactions : Telmisartan may increase the hypotensive effect of other antihypertensive agent. Serum lithium level monitoring is advisable during concomitant use of lithium with telmisartan. Other interaction of clinical significance has not been identified.

Overdose : Symptoms of overdose include: hypotension, dizziness, tachycardia, bradycardia.

Storage : Store below 30°C in a dry place. Keep all medicines out of reach of children.

Packing : Telmicard : Each box contains 2 x 14's tablet in blister pack.