UNIAZ-T

To be sold by retail on prescription of R.M.P only

Abbreviated Prescribing information for UNIAZ-T (Azelnidipine and Telmisartan Tablets)
[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Uniaz-T contains telmisartan and azelnidipine. Telmisartan is an orally active and specific angiotensin II receptor (type AT1) antagonist. Telmisartan displaces angiotensin II with very high affinity from its binding site at the AT1 receptor subtype, which is responsible for the known actions of angiotensin II. Angiotensin II is formed from angiotensin I in a reaction catalyzed by angiotensin-converting enzyme (ACE, kininase II). Angiotensin II is the principal pressor agent of the renin-angiotensin in system, with effects that include vasoconstriction, stimulation of synthesis and release of aldosterone, cardiac stimulation, and renal reabsorption of sodium. Telmisartan blocks the vasoconstrictor and aldosterone-secreting effects of angiotensin II by selectively blocking the binding of angiotensin II to the AT1 receptor in many tissues, such as vascular smooth muscle and the adrenal gland. Azelnidipine is a dihydropyridine calcium channel blocker. This drug represents lowering of the blood pressure by expanding the blood vessels based on L type and T type Ca channel antagonizing effect (inhibits trans-membrane Ca2+ influx through the voltage-dependent channels of smooth muscles in vascular walls).

DOSAGE AND ADMINISTRATION:

Adults

The daily recommended dose is one film-coated tablet. UNIAZ-T is not recommended in Paediatric population.

CONTRAINDICATION: Known hypersensitivity to azelnidipine and telmisartan or to any of the excipients. Pregnant women or women who has a possibility to conceive.

WARNINGS & PRECAUTIONS: Telmisartan and Azelnidipine should not be initiated during pregnancy. Drugs that act directly on the renin-angiotensin system can cause injury and death to the developing fetus (Fetal Toxicity). This product should be used with caution in patients with renal and hepatic impairment, diabetic patients (treated with insulin or antidiabetics) and severe obstructive coronary artery disease.

DRUG INTERACTION:

Telmisartan: The blood pressure lowering effect of Telmisartan can be increased by concomitant use of other antihypertensive medicinal products. Interaction risk may increase in case of treatment combination with other medicinal products that may also provoke hyperkalaemia (salt substitutes containing potassium, potassium-sparing diuretics, ACE inhibitors, angiotensin II receptor antagonists, non-steroidal anti-inflammatory medicinal products (NSAIDs, including selective COX-2 inhibitors), heparin, immunosuppressive (cyclosporin or tacrolimus), and trimethoprim. Concomitant use of digoxin and lithium with telmisartan requiring caution. NSAIDs (i.e. acetylsalicylic acid at anti-inflammatory dosage regimens, COX-2 inhibitors and non-selective NSAIDs) and corticosteroids may reduce the antihypertensive effect of angiotensin II receptor antagonists.

Azelnidipine: Strong inhibitors of CYP3A4 (cytochrome P450 3A4) (e.g., ketoconazole, itraconazole, ritonavir, indinavir) may increase the plasma concentrations of Azelnidipine to a greater extent. Monitor for symptoms of hypotension and edema when Azelnidipine is co-administered with CYP3A4 inhibitors. Precautions should be taken at the time of simultaneous

usage of Azelnidipine with digoxin, cimetidine, imatinib mesylate, grape fruit juice, rifampicin and phenytoin.

ADVERSE REACTIONS: Fatigue, asthenia, oedema, urinary tract infection, sepsis, anaphylactic reaction, hyperkalaemia, hypoglycaemia, visual disturbance, bradycardia, tachycardia, orthostatic hypotension, pruritus, hepatic function abnormal, blood creatinine increased, blood urea nitrogen (BUN) increased, creatine phosphokinase increased, renal impairment including acute renal failure, interstitial lung disease, jaundice, atrioventricular block, sinus arrest, drowsiness, headache, and dizziness.

MARKETED BY:
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IN/ UNIAZ-T 8, 40mg and 8, 80mg/SEP-20/01/ABPI
(Additional information is available on request)