

## UNIAZ

**For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only**  
abbreviated prescribing information for UNIAZ ( Azelnidipine Tablets IP 8 mg and 16 mg) [Please refer the complete prescribing information available at [www.torrentpharma.com](http://www.torrentpharma.com) ]

**PHARMACOLOGICAL PROPERTIES:** Pharmacotherapeutic group: Dihydropyridine Ca antagonist. This drug represents lowering of the blood pressure by expanding the blood vessels based on L type and T type Ca channel antagonizing effect.

**INDICATION:** UNIAZ 8 indicated for the treatment of Stage-I hypertension and UNIAZ 16 indicated for the treatment of Stage-II hypertension.

**DOSAGE AND ADMINISTRATION:** Uncoated tablets 8 mg and 16 mg. should be taken as directed by Physician.

**CONTRAINDICATION:** Hypersensitivity to active ingredients or to any of the excipients. Pregnant women or women who has a possibility to conceive. Patients who are using Azole antifungal drug (Itraconazole, Miconazole etc), HIV Protease inhibitor (Ritonavir, Saquinavir, Indinavir etc.).

**WARNINGS & PRECAUTIONS:** Must be used with caution towards the Patients who are having serious Liver/kidney function failure (This drug will metabolize in the Liver. Further, generally for the patients who are having a serious kidney function failure, there is a possibility of pressure drop along with the decrease in kidney function).- Aged Individual. *Important and basic instructions:* When the intake of calcium antagonists is suspended suddenly, in case of discontinuation of this product, gradual dose reduction should be made and conduct sufficient observations since there are cases where it is reported that the symptoms are worsening. Further, it must be instructed to patients that the drug must not be discontinued without any direction unless until given by the physician. There are possibilities of the occurrence of excessive low blood pressure very rarely due to the intake of this drug, therefore, in that case please take appropriate measures such as reducing the dosage or discontinuing the intake of the drug. - Must be cautious while working at heightened place, travelling in train, operating with machines which are dangerous since giddy feeling can be felt based on the antihypertensive effect.

**DRUG INTERACTIONS:** *Azole antifungal drug Itraconazole, Miconazole* etc. It is reported that AUC of this drug will increase 28 times when this drug is simultaneously used with Itraconazole. *HIV Protease inhibitor (Ritonavir, Saquinavir, Indinavir:* There is a possibility of increased effect of this drug due to simultaneous usage. *Other depressor drug:* There is a possibility of excess low blood pressure. If it is required to reduce the dosage of this drug or other depressor drug.

*Digoxin:* It is reported that C<sub>max</sub> and AUC of digoxin increases up to 1.5 and 1.3 times respectively due to simultaneous usage. If it is required to reduce the dosage of digoxin. *Cimetidine, Imatinib mesylate, Delavirdine mesylate, Macrolide antibiotic, Erythromycin and Clarithromycin* etc. There will be augmentation in the effect due to the simultaneous usage of this drug. If required, reduce the dosage of this drug or suspend the intake of these drugs. *Simvastatin:* It is reported that AUC of Simvastatin increases to 2.0 times due to simultaneous usage. If required, suspend the intake of this drug or Simvastatin. *Cyclosporine, Benzodiazepine drug, Diazepam, Midazolam, Triazolam etc. or orally-active progestin / estrogenic hormone Oral contraceptives:* There will be augmentation in the effect due to the simultaneous usage of this drug. If required, reduce the dosage of this drug or these medicines. *Tandospirone citrate:* There will be augmentation in the effect due to the simultaneous usage of this drug. If required, reduce the intake of this drug or suspend the intake of Tandospirone citrate. *Rifampicin, Phenytoin & Phenobarbital:* There will be decrease in the effect due to the simultaneous usage of this drug. *Grape fruit juice:* It is reported that there will be an increase in the blood concentration level while using this drug. Since there is a possibility of augmentation of pressure reducing effect, be cautious not to drink grape fruit juice while the patient is under medication of this drug.

**ADVERSE REACTIONS:** *Serious side effects:* Liver function failure, Jaundice: Since there were cases which showed liver function failure, jaundice due to increase of AST (GOT), ALT (GPT), 'Y-GTP, please conduct enough observation and in case when the abnormality is recognized, stop the

intake and must take appropriate measures. Atrioventricular block, Sinus arrest, Bradycardia: Since there were cases where atrioventricular block, sinus arrest and bradycardia were shown, in case when dizziness, wobbling is recognized, stop the intake and must take appropriate measures.

**Other side effects:** **Hypersensitivity:** Rash, itching, Swelling of blood vessel. **Psychoneurotic system:** Headache / Heavy headed feeling, wobbling, dizziness, light headedness, Drowsiness. **Digestive organ:** Gastric distress, Nausea, Constipation, abdominal pains, Diarrhoea, Enlarged gums, Mouth ulcer. **Circulatory organ:** Palpitation, Sensation of warmth, Skin flushing on face portion **Blood:** Drastic increase in eosinophil. **Liver:** Increase in ALT (GPT), Increase in AST (GOT), LDH increase, Liver function abnormality, ALP increase, Increase in total bilirubin. **Urinary organs:** Increase in BUN, Increase in creatinine, Increase in urine hyaline cast, frequent urination. **Others:** Increase in urinary acid, increase in overall cholesterol, Increase in CK (CPK), Increase in potassium, Fatigue, abnormal sensation (Light headedness, bad mood etc.) Reduction in potassium, Swelling, Numbness. Milky fluid in the abdomen<sup>Note3</sup>

**MARKETED BY:**



TORRENT PHARMACEUTICALS LTD.

**IN/UNIAZ 8 mg, 16 mg/APR-20/01/PI**

(Additional information is available on request)