

UNIAZ

For the use of a Registered Medical Practitioner or Hospital or a Laboratory only

Abbreviated Prescribing information for UNIAZ [Azelnidipine Tablets I.P 8 mg and 16 mg]

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: 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.

INDICATIONS: *UNIAZ 8* For the treatment of Stage – I Hypertension. *UNIAZ 16* For the treatment of Stage – II hypertension.

DOSAGE AND ADMINISTRATION: Normally, UNIAZ must be used orally only one time after breakfast for an adult. In addition, start the dosage from 8mg or still further low dosages one time and based on the symptoms the dosage must be increased or decreased appropriately but the maximum dosage per day shall be up to 16 mg.

CONTRAINDICATIONS: a) Hypersensitivity to active ingredients or to any of the excipients. b) Pregnant women or women who has a possibility to conceive. c) Patient who are using azole antifungal drug (itraconazole, miconazole etc), HIV Protease inhibitor (Ritonavir, Saquinavir, Indinavir etc).

WARNINGS AND PRECAUTIONS: a) Patients who are having serious Liver/Kidney function failure. b) 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. c) 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. d) 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 INTERACTION: Azole antifungal drugs (e.g., Itraconazole, Miconazole) and HIV protease inhibitors (e.g., Ritonavir, Saquinavir, Indinavir) may increase the drug's effect by inhibiting CYP3A4, leading to reduced clearance and potential augmentation of its effects. Other depressor drugs may cause excessive low blood pressure, requiring a reduction in dosage. Similarly, the C_{max} and AUC of digoxin increase, necessitating a reduction in its dosage. Drugs such as cimetidine, imatinib, delavirdine, macrolides (e.g., erythromycin and clarithromycin) augment the effect of certain drugs by inhibiting CYP3A4, and dosage reduction or suspension may be required. The AUC of simvastatin increases, especially in individuals with kidney function failure, and dosage adjustments should be made accordingly. Cyclosporine may augment the effect of certain drugs due to similar CYP3A4 inhibition. Benzodiazepines (like diazepam, midazolam, and triazolam) and oral contraceptives can increase the effect of the drug, warranting dosage reduction or suspension. Tandospirone citrate may augment the blood pressure-lowering effect when used with certain drugs, requiring cautious use and dosage reduction if necessary. Rifampicin, phenytoin, and phenobarbital decrease the drug's effect due to the metabolizing enzyme-inducing effect. Lastly, grapefruit juice increases the drug's blood concentration, potentially worsening the blood pressure-lowering effect, and should be avoided while on medication.

ADVERSE REACTION: Rash, itching, swelling of blood vessel, headache, dizziness, drowsiness, light-headedness, gastric distress, nausea, constipation, abdominal pain, diarrhea, enlarged gums, mouth ulcers, palpitations, warmth sensation, skin flushing on face, drastic increase in eosinophils, increased ALT, AST, LDH, ALP, abnormal liver function, increased total bilirubin, Increased BUN, creatinine, uric acid, frequent urination, hyaline casts in urine, Increased cholesterol, CK (CPK), potassium, fatigue, abnormal sensations (bad mood), reduction in potassium, swelling, numbness, milky fluid in the abdomen.

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IN/UNIAZ 8 mg, 16 mg/AUG-25/02/ABPI