

## Uniaz - CH

**For the use of a Registered Medical Practitioner or Hospital or a Laboratory only.**  
Abbreviated Prescribing information for Uniaz CH 8+6.25 / 8+12.5 mg (Azelnidipine and  
Chlorthalidone Tablets)

[Please refer the complete prescribing information available at [www.torrentpharma.com](http://www.torrentpharma.com)]

### PHARMACOLOGICAL PROPERTIES:

**Mechanism of action:** Azelnidipine binds to membrane voltage-dependent L-type and T type calcium channels, reducing the influx of calcium into the cell, thereby relaxing the smooth muscle of peripheral vascular or coronary.

Chlorthalidone is a thiazide-like diuretic which acts primarily on the distal renal tubule (early convoluted part), inhibiting  $\text{Na}^+\text{Cl}^-$  reabsorption (by antagonising the  $\text{Na}^+\text{Cl}^-$  cotransporter) and promoting  $\text{Ca}^{++}$  reabsorption (by an unknown mechanism). The enhanced delivery of  $\text{Na}^+$  and water to the cortical collection tubule and/or the increased flow rate leads to increased secretion and excretion of  $\text{K}^+$  and  $\text{H}^+$ .

**DOSAGE AND ADMINISTRATION:** As directed by physician.

### CONTRAINDICATION:

Women who may possibly be pregnant or are pregnant, history of hypersensitivity to any of the component of the drug, concomitant administration with azole antifungals (itraconazole, miconazole, etc.) or HIV protease inhibitors (ritonavir, saquinavir, indinavir, etc.), anuria, severe hepatic or renal failure (creatinine clearance  $<30\text{ml/min}$ ), refractory hypokalaemia, hyponatraemia and hypercalcaemia, symptomatic hyperuricaemia (history of gout or uric acid calculi), untreated Addison's disease and concomitant lithium therapy, severe hepatic impairment

**WARNINGS & PRECAUTIONS:** Elderly patients, patients with liver/kidney function abnormalities, abrupt discontinuation of drug, choroidal effusion, acute myopia and secondary angle-closure glaucoma, electrolyte disturbances such as hypokalaemia, hypomagnesaemia, hyperglycaemia and hyponatraemia, gout, increases in plasma concentrations of total cholesterol, triglycerides, or low-density lipoprotein cholesterol.

**DRUG INTERACTION:** Azole antifungal drug (itraconazole, miconazole), HIV Protease inhibitor (ritonavir, saquinavir, indinavir etc.), digoxin/digitalis, cimetidine, imatinib, delavirdine, Macrolide antibiotic (erythromycin, clarithromycin), simvastatin, Benzodiazepine drug (diazepam, midazolam, triazolam etc.) orally-active progestin / estrogenic hormone, oral contraceptive, tandospirone, rifampicin, phenytoin, phenobarbital, grape fruit juice, curare derivatives and antihypertensive drugs (e.g. guanethidine, methyldopa,  $\beta$ -blockers, vasodilators, calcium antagonists and ACE inhibitors), corticosteroids, ACTH,  $\beta_2$  – agonists, amphotericin and carbenoxolone, insulin and oral anti-diabetic agents, anticholinergic agents (eg atropine, biperiden), cholestyramine, allopurinol, diazoxide, cytotoxic agents (eg cyclophosphamide, methotrexate). calcium salts and vitamin D, cyclosporine, lithium

### ADVERSE REACTIONS:

Azelnidipine: liver function failure, jaundice, atrioventricular block, sinus arrest, bradycardia, rash, itching, swelling of blood vessel, headache / heavy headed feeling, wobbling, dizziness, light headedness, drowsiness, gastric distress, nausea, constipation, abdominal pains, diarrhoea, enlarged gums, mouth ulcer, palpitation, sensation of warmth, skin flushing on face portion, drastic increase in eosinophil, increase in ALT (GPT), increase in AST (GOT), LDH

increase, liver function abnormality, ALP increase, increase in total bilirubin, increase in BUN, increase in creatinine, increase in urine hyaline cast, frequent urination, 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.

Chlorthalidone: hypokalaemia, hyperuricaemia, and rise in blood lipids, hyponatraemia, hypomagnesaemia and hyperglycaemia, gout, hypercalcaemia, glycosuria, worsening of diabetic metabolic state, hypochloraemic alkalosis, urticaria and other forms of skin rash, photosensitisation, intrahepatic cholestasis or jaundice, postural hypotension, cardiac arrhythmias, Dizziness, paraesthesia, headache, loss of appetite and minor gastrointestinal distress, mild nausea and vomiting, gastric pain, constipation and diarrhoea, pancreatitis, Thrombocytopenia, leucopenia, agranulocytosis and eosinophilia, impotence, Idiosyncratic pulmonary oedema (respiratory disorders), allergic interstitial nephritis

**Marketed by:**



TORRENT PHARMACEUTICALS LTD.

**IN/UNIAZ CH 8,6.25mg and 8,12.5mg/MAR-21/01/ABPI**

(Additional information is available on request)