

# Insert for prescribing information

#### Presentation

Cetri-Mak® 10 mg Tablet: Each film-coated tablet contains Cetirizine Dihydrochloride BP 10 mg.

### **Pharmacology**

Cetirizine is a potent antihistaminic with a low potential for drowsiness at pharmacologically active doses and with additional anti-allergic properties. It is a selective H1-antagonist with negligible effects on other receptors and so virtually free from anti-cholinergic and anti-serotenic effects. Cetirizine inhibits the histamine mediated early phase of the allergic reaction and also reduces the migration of inflammatory cells and the release of mediators associated with the late phase allergic response.

#### **Pharmacokinetics**

Cetirizine dihydrochloride 10 mg achieves peak plasma concentrations of 257 mcg/L within one hour of administration (980 mcg/L in children). Food does not affect the extent of absorption, but it may slightly reduces the rate. Peak blood levels 0.3 micrograms/ml are reached between 30 & 60 minutes after administration of 10 mg dose of Cetirizine. Its plasma half-life is approximately 11 hours. Absorption is very consistent from one subject to the next. Its renal clearance is 30 ml/minute and the excretion half-life is approximately 9 hours. Cetirizine is strongly bound to plasma proteins.

### Indications

Cetirizine is indicated for the treatment of Perennial Allergic Rhinitis, Seasonal Allergic Rhinitis (hay-fever) & Chronic Idiopathic Urticaria and other histamine related cutaneous problems like itching etc.

### **Dosage & Administration**

Tablet

Adults ≥12 years.: 1 tablet daily or ½ tablet twice daily. Children 2-6 years: 1/2 tablet daily or 1/4 tablet twice daily.

#### Contraindication

Cetirizine is contraindicated in patients who have shown hypersensitivity or idiosyncrasy to it or to its parent compound hydroxyzine.

#### **Side Effects**

Cetirizine is well tolerated. It does not produce anticholinergic effects. Lower incidence of sedation. headache, dry mouth and gastro-intestinal disturbances.

# **Warning & Precaution**

Caution should be exercised when driving a car or operating a heavy machinery. Concurrent use of Cetirizine with alcohol or other CNS depressants should be avoided because additional reduction in alertness and additional impairment of CNS performance may occur.

# **Use in Pregnancy & Lactation**

Pregnancy category "B". Cetirizine should be used in pregnancy only if clearly needed. Cetirizine has been reported to be excreted in human milk and thus, use of Cetirizine in lactating mother is not recommended.

## **Drug-interactions**

There is no reports of potential hazardous or beneficial drug interactions. Cetri-Mak® does not potentiate the effect of alcohol or benzodiazipines.

# Storage

Store at temperature not exceeding 30° C in a dry place. Protect from light.

### **Commercial Packs**

Cetri-Mak® 10 mg Tablet: Each box contains 5x10's tablets in blister strip.

For child safety: Keeping medicines out of reach



Manufactured by Maks Drug Limited Plot No- S 58-59, BSCIC I/A, Konabari, Joydebpur, Gazipur, Bangladesh.