CETRIZIN

Each tablet contains cetirizine dihydrochloride 10 mg

DESCRIPTION
Long round end biconvex tablet with bisec line on one side and coated with white film.

PROPERTIES
Cetirizine hydrochloride is a long-acting antihistamine with some mast-cell stabilising activity. Its principal effects are mediated via selective inhibition of peripheral H_1 receptor. Cetirizine is devoid of any significant anticholinergic or antiserotonergic effect.

Cetirizine was shown to inhibit certain effects produced by exogenous histamine. It was also shown to inhibit the cutaneous reaction induced by VIP (Vasoactive Intestinal Polypeptide) and substance P, neuropeptides which are believed to take part in the allergic reaction.

Cetirizine blocks histamine-induced bronchoconstriction in asthmatic patients and also reduces the allergic reactions induced by specific allergens.

Cetirizine is rapidly absorbed from gastrointestinal tract after oral administration. Peak plasma concentration is attained in about one hour. Food delays the time to peak plasma concentrations, but does not decrease the amount of drug absorbed. It is highly bound to plasma proteins (93 %) and has elimination half-life of about 10 hours. Cetirizine has been detected in breast milk. It is excreted primarily in the urine and mainly as unchanged drug. Cetirizine does not appear to cross the blood-brain barrier to a significant extent.

INDICATIONS
Cetrizin is indicated for treatment of seasonal rhinitis, perennial allergic rhinitis, pruritus and urticaria.

CONTRAINDICATIONS
Cetrizin is contraindicated in patients with a history of hypersensitivity to cetirizine or any of its ingredients.
Cetrizin is also contraindicated in lactating women.

SIDE EFFECTS / ADVERSE REACTIONS
Headache, dizziness, drowsiness, agitation, dry mouth and gastrointestinal discomfort have been reported. Incidence of sedation may increase when recommended doses of cetirizine are exceeded.

PRECAUTIONS / WARNINGS
Activities Requiring Mental Alertness: In clinical trials the occurrence of somnolence has been reported in some patients taking cetirizine. Due caution should therefore be exercised when driving a car or operating potentially dangerous machinery.

Concurrent use of cetirizine with alcohol or other CNS depressants should be avoided because mental alertness may be impaired.

Pregnancy and Lactation
Adequate and well-controlled studies in human have not been done. However, as a precaution, ***Cetrizin*** should not be administered during the first 3 months of pregnancy since animal studies have shown that it

could cause foetal abnormalities when given in doses substantially above the human therapeutic range. ***Cetrizin*** is also contraindicated in lactating women since it is excreted in breast milk.

Paediatric
The safety and effectiveness of cetirizine in paediatric patients under the age of 2 years have not yet been established.

DRUG INTERACTIONS
Caution should be exercised when sedatives are taken together because cetirizine has been shown to cause mild dose-related CNS effects (e.g. sedation). To date, there is no known interaction with other drugs.

RECOMMENDED DOSAGE, DOSAGE SCHEDULE & ROUTE OF ADMINISTRATION
Adult and children over 12 years:
One tablet once daily. Dosage may be increased to 20 mg a day, depending on severity of symptoms and patient response.

Note: In patients with reduced creatinine clearance, a starting dose of 5mg is recommended.

Children 6 years and above:
10 mg daily, either as 2 divided doses or as a single dose.

SYMPTOMS & TREATMENTS FOR OVERDOSAGE AND ANTIDOTES(S)
Symptoms:
Severe drowsiness

Treatment:
There is no specific antidote for overdosage with cetirizine. Treatment should be symptomatic and supportive with possible utilization of the following:
- Induction of emesis. However, precaution against aspiration is necessary especially in infants or children.
- Gastric lavage

Precautions should be taken against the use of stimulants (analeptic agents) because they may cause seizures.

PACKING / PACK SIZES
Aluminium – PVC blister strip of 10 tablets per strip. Boxes of 10 and 50 blisters each.

STORAGE CONDITIONS, USER INSTRUCTIONS & PHARMACEUTICAL PRECAUTIONS
Store below 30 °C.
Protect from light.
Keep out of reach of children.
Jauhi daripada kanak-kanak.

Shelf-life: Please refer to the outer box label.

Manufactured by:
T.O. CHEMICALS (1979) LTD.,
53 Lieb-Klong 7 Road, Moo 4,
Bueng Kham Phroi, Lam Luk Ka,
Pathumthani 12150, Thailand.

Revision Date: August 2019