ZERTIN TABLET

DESCRIPTION:
White to off-white, oblong shaped film coated tablets with a score on one side.

COMPOSITION:
Each tablet contains: Cetirizine Dihydrochloride 10 mg

ACTIONS & PHARMACOLOGY:
Cetirizine, a human metabolite of hydroxyzine, is a potent antihistamine with a low potential for drowsiness at normal therapeutic doses. Its principal effects are mediated via selective inhibition of peripheral H1 receptors. In experimental animals, cetirizine has been shown to be an anti-H1 agent without any significant anticholinergic or antiserotonin effects. At pharmacological active doses, cetirizine does not induce sedation and behavioural changes due to the fact that it does not cross the blood-brain barrier.

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

Cetirizine inhibits the histamine-mediated "early" phase of the cutaneous allergic reaction and also reduces the migration of inflammatory cells, eg eosinophils and the release of mediators associated with the "late" cutaneous allergic response.

Cetirizine reduces bronchial hyper-reactivity to histamine in the asthmatic patient and the allergic reaction induced by specific allergens. These effects are obtained without any central effects being demonstrated. Cetirizine is rapidly and almost completely absorbed following oral administration. Absorption is very consistent from one subject to the next. Peak plasma concentrations are generally obtained within 1 hour under fasting conditions. The extent of absorption is not reduced by food; however, the rate of absorption is reduced and the peak levels are expected about 3 hours after dosing. After repeated oral administration, the daily urinary excretion of unchanged cetirizine is about 65% of the dose. The absorption and the elimination of cetirizine are independent of the dose. Its renal clearance is 30ml/min. The plasma half-life of cetirizine is approximately 9 hours. This value is increased in patients with reduced renal function. Cetirizine is strongly bound to human plasma proteins (93%).

INDICATIONS:
Adults and children of 3 years or above – symptomatic treatment of seasonal rhinitis, perennial allergic rhinitis and urticaria of allergic origin.

CONTRAINDICATIONS:
Contraindicated in patients with known hypersensitivity of any of the ingredients of Zertin Tablet, to hydroxyzine or to any piperazine derivatives.

Patients with severe renal impairment at less than 10 ml/min creatinine clearance.

SIDE EFFECTS / ADVERSE REACTIONS:
There have been occasional reports of mild and transient side effects such as headache, dizziness, drowsiness, agitation, dry mouth, gastrointestinal discomfort, and hypersensitivity.

WARNING AND PRECAUTIONS:
Precaution is recommended if alcohol is taken concomitantly.

Caution should be taken in patients with predisposition factors of urinary retention (e.g. spinal cord lesion, prostatic hyperplasia) as cetirizine may increase the risk of urinary retention.

Caution in epileptic patients and patients at risk of convulsions is recommended.

Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Pruritus and/or urticaria may occur when cetirizine is stopped, even if those symptoms were not present before treatment initiation. In some cases, the symptoms may be intense and may require treatment to be restarted. The symptoms should resolve when the treatment is restarted.

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.

Use in pediatric patients: The safety and effectiveness of cetirizine in pediatric patients under the age of 2 years have not yet been established.

PREGNANCY AND LACTATION:
Pregnancy

For cetirizine prospectively collected data on pregnancy outcomes do not suggest potential for maternal or foetal/embryonic toxicity above background rates.

Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/fetal development, parturition or postnatal development. Caution should be exercised when prescribing to pregnant women.

Lactation

Cetirizine passes into breast milk. A risk of side effects in breastfed infants cannot be excluded. Caution should be exercised when prescribing cetirizine to lactating women.

DRUG INTERACTIONS:
To date, there are no known interactions with other drugs. As with other antihistamines it is advisable to avoid excessive alcohol consumption. If sedatives are also being taken, cetirizine should be used with caution.

DOSAGE AND ADMINISTRATION:
Adults
10 mg once daily.
Children ≥ 6 years
10 mg daily, either 5 mg twice daily or 10 mg once daily.
Children 3-6 years
5 mg daily, either 2.5 mg twice daily or 5 mg once daily.
Patients with renal insufficiency
Dosage should be reduced to 1/2 the daily dose.

It is advisable to take the drug with a little liquid during the evening meal since the symptoms for which the product is given usually appear during the night. The dose may be taken as 5 mg in the morning and 5 mg in the evening in patient affected by side effects.

ROUTE OF ADMINISTRATION:
Oral administration

EFFECTS ON ABILITY TO DRIVE OR USE MACHINE:
Objective measurements of driving ability, sleep latency and assembly line performance have not demonstrated any clinically relevant effects at the recommended dose of 10 mg. However, patients who experience somnolence should refrain from driving, engaging in potentially hazardous activities or operating machinery.
Patients intending to drive, engaging in potentially hazardous activities or operating machinery should not exceed the recommended dose and should take their response to the medicinal product into account.

SYMPTOMS AND TREATMENT FOR OVERDOSAGE:
Drowsiness can be a symptom of overdosage, occurring from administration of 50 mg of cetirizine as a single dose. In children agitation can occur. To date, there is no specific antidote. In case of massive overdosage, gastric lavage should be performed together with the usual supportive measures. Routine observation should also be carried out regularly.

PRESENTATION:
Blister of 10 tablets. Boxes of 10 or 50 strips

STORAGE:
Store in a dry place below 30°C.
Protect from light.
Keep the container tightly closed.
Keep out of reach of children.
Jauhkan daripada kanak-kanak.

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