For registration
Artwork of insert **"ZIRIN"** (PCL) code ***RI-C148-M10-00-00***
Size : 132x 186 mm

ZIRIN
Clearcap

Composition :
Each Softgel Capsule Contains
Cetirizine dihydrochloride 10 mg

Inactive Ingredients :
Polyethylene glycol 400, Sodium hydroxide, Gelatin, Glycerin, Purified water.

Pharmacology :
Cetirizine hydrochloride is a second generation, long-acting antihistamine. The drug has been characterized as a selective, peripheral H1-receptor antagonist. It is the carboxylic acid metabolite of hydroxyzine. The increased its polarity may decrease distribution of the drug into the central nervous system (CNS), resulting in reduced potential for adverse CNS effects compared with some first generation antihistamine.

Pharmacokinetics :
Cetirizine hydrochloride is rapidly absorbed from the gastrointestinal tract. Following oral administration of 10- or 20- mg doses of drug in healthy adult, peak plasma concentrations of 257-384 or 580 ng/ml, respectively, are achieved in about 1 hour. The antihistaminic effect of the drug (as measured by suppression of the wheal and flare response induced by intradermal injection of histamine) was apparent within 20 and 60 minutes in 50 and 95% of individuals, respectively, and persisted for about 24 hours.

Distribution of drug and its metabolites into human body tissues and fluids has not been fully elucidated. The substantial polarity of drug apparently limits distribution of the drug into the CNS. Drug is distributed into milk in humans and animals, approximately 93% bound to plasma proteins; protein binding appears to be independent of the concentration of the drug ranging from 25-1000 ng/ml, which includes usual therapeutic plasma concentrations.

Elimination may undergo biphasic elimination with an initial distribution half-life of about 3 hours and mean terminal elimination half-life about 8.3 hours (ranges: 6.5-10 hours). About 80% of the dose is excreted within 5 days, mainly (more than 50%) as unchanged drugs; most excretion occurs within 24 hours.

Indication :
Symptomatic relief of seasonal allergic rhinitis, perennial allergic rhinitis, and chronic idiopathic urticaria.

Dosage :
Take one capsule once daily or as directed by a physician.

Mode of Administration : Oral Administration.

Contraindications :
Cetirizine hydrochloride is contraindicated in patients who are hypersensitive to cetirizine, hydroxyzine, or any ingredients in the formulation.

Warnings & Precautions :
• Drowsiness may occur.
• Avoid alcohol drinks.
• Alcohol, sedatives, and tranquilizers may increase drowsiness.
• Be careful when driving a motor vehicle or operating machinery.

Drug Interactions :
Because the cetirizine hydrochloride is metabolized only minimally in the liver and is excreted mainly uncharged in urine, it may have a low potential for adverse drug interactions associated with metabolic enzyme systems.

Pregnancy & Lactation :
Because there are no adequate and controlled studies to date using cetirizine hydrochloride in pregnant women and animal studies are not always predictive of human response, drug should be used during pregnancy only when clearly needed. The use of cetirizine hydrochloride in lactating women is not recommended.

Side Effects :
Somnolence, fatigue, headache, dry mouth, pharyngitis, dizziness, abdominal pain, coughing, diarrhea, istaxis, bronchospasm, nausea and vomiting.

Overdose & Treatment :
Overdosage has been reported in individuals receiving cetirizine hydrochloride. Somnolence was reported in the adult who ingested 150 mg of drug; no other adverse effects, including clinical manifestations, abnormal blood chemistry, or abnormal hematology occurred in this individual. Restlessness and irritability followed by drowsiness were reported in an 18-month old child who ingested about 180 mg of drug. In acute overdosage, treatment should include symptomatic and supportive measures, taking into account the possibility of any concomitantly ingested drugs.

Shelf Life : Two years from manufacturing date.

Packaging : Softgel capsules in unit carton containing 5x10 capsules blister packed.

Store below 30°C in a dry place, away from direct sunlight.
Read the instructions carefully before use.
Do not use the product after the expiry date.
Do not use the product if there are any significant changes in appearance of the capsules.
Keep out of reach of children.

Manufactured under license from :
MEGA LIFESCIENCES (AUSTRALIA) PTY. LTD.
Victoria 3810, Australia

Manufactured by :
MEGA LIFESCIENCES Public Company Limited
384, Moo 4, Soi 6, Bangpoo Industrial Estate, Pattana 3 Road, Phraeksa, Mueang, Samutprakarn 10280, Thailand

RI-C148-M10-00-00

*Font : Rubrik size 5.36 pt

Artwork Check / Layout Check

PC TEAM		PRODUCTION		RA
Provide by : *Supawan* Date : *31-May-16*	PC Check	Production Check 1 :	☐ Pass : …… ☐ Not pass : ……	Need to send for customer approval
Department head approved : ……	☐ Pass : …… ……	Production Check 2 :	☐ Pass : …… ☐ Not pass : ……	☐ Yes, please send …… ……
Date : ……	☐ Not Pass : …… ……	Production Department Head :	☐ Pass : …… ☐ Not pass : ……	☐ Not require …… ……
Final artwork from RA/Customer approved : ……				
……Date : ……				