SUMMARY OF PRODUCT CHARACTERISTICS

1.0 Name of the Medicinal Product

1.1 Product Name

ZIRIN Clearcap

1.2 Strength

Cetirizine Dihydrochloride 10 mg

1.3 Pharmaceutical Dosage Form

Soft gelatin capsules

2. Qualitative and Quantitative Composition

2.1 Qualitative Declaration

Recommended International Non-proprietary name (INN): Cetirizine Dihydrochloride

2.2 Quantitative Declaration

Each softgel capsule contains:

Cetirizine Dihydrochloride……...10.00 mg

3. Pharmaceutical Form

Soft gelatin capsules.

Clear colorless oily liquid filled in 10 minim, oval shape, natural color, soft gelatin capsule.

4. Clinical Particulars

4.1 Therapeutic Indications

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

4.2 Posology and method of administration

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

Method of Administration: Oral

4.3 Contraindications

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

4.4 Special Warnings and Precautions for Use

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

4.5 Interaction with other drugs, other forms of 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.

4.6 Use in Pregnancy and 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.

4.7 Effects on Ability to Drive and operate Machines

Cetirizine Dihydrochloride may impair ability to perform hazardous activities requiring mental alertness or physical co-ordination (e.g., operating machinery, driving a motor vehicle).

4.8 Adverse/ Undesirable/ Side Effects

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

4.9 Overdose

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.

5. Pharmacological properties

5.1 Pharmacodynamic Properties

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.

5.2 Pharmacokinetic Properties

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.

5.3 Preclinical Safety Data

The animal and genetic toxicology studies indicate that cetirizine, even when administered chronically and at very high dosage, has inherently low toxicity. The drug showed no carcinogenic potential, is not mutagenic or clastogenic, it did not have any significant or deleterious impact on reproductive cycles and could not be demonstrated to be a teratogen.

6. Pharmaceutical Particulars

6.1 List of Excipients

Capsule Fill: Polyethylene glycol 400, Sodium hydroxide, Purified Water

Capsule Shell: Gelatin, Glycerin, Purified water

6.2 Incompatibilities

None.

6.3 Shelf Life

24 months

6.4 Special Precautions for Storage

Store below 30°C in a dry place, away from direct sunlight.

7. Marketing Authorization Holder

MEGA LIFESCIENCES Public Company Limited

384 Moo 4, Soi 6, Bangpoo Industrial Estate,

Pattana 3 Road, Phraeksa, Mueang,

Samutprakarn 10280, Thailand.

8. Marketing Authorization Number

9. Date of first Registration/ Renewal of the Registration

10. Date of revision of the text