SUMMARY OF PRODUCT CHARACTERISTICS (SPC)

1. Name of the medicinal product

CEPROLEN EYE/EAR DROPS (Ciprofloxacin Hydrochloride Solution).

2. Qualitative and quantitative composition

Ciprofioxacin Hydrochloride USP
equivalent to Ciprofioxacin USP..... % w/v
Benzalkonium Chloride Solution BP .....0.02% v/v (as preservative)
Sterile aqueous base.....q.s.

For a full list of excipients see section 6.1.

3. Pharmaceutical Form

Ophthalmic Solution.

4. Clinical particulars:

4.1 Therapeutic indications:

Eye: Acute and subacute conjunctivitis, mucopurulent conjunctivitis, blepharoconjunctivitis, blepharitis, bacterial corneal ulcer with or without hypopyon, bacterial keratitis and kerato conjunctivitis, chronic dacryocystitis, meibomanitis, preoperative prophylaxis in ocular surgery, treatment of post operative infections.

Ear: Otitis externa, acute otitis media, chronic suppurative otitis media and prophylaxis during otic surgeries such as mastoid surgery.

4.2 Posology and method of administration:

As directed by the physician.

4.3 Contraindications:

Hypersensitivity to any of the ingredients in the formulation.

4.4 Special warnings and precautions for use:

Do not touch the nozzle tip to any surface since this may contaminate the solution. Do not use the solution if tamper evident ring of cap is broken or missing. This preparation is for external use only and it should not be used for injection. Use the solution within one month after opening the vial. If irritation persists or increases discontinue the use and consult physician.

Ciprofloxacin is generally not recommended for use in children and adolescents and during pregnancy and breast feeding.

4.5 Interaction with other medicinal products and other forms of interaction:

Specific drug interaction studies have not been conducted with ophthalmic ciprofloxacin. Given the low systemic concentration of ciprofloxacin following topical ocular administration of the product, drug interactions are unlikely to occur.

If more than one topical ophthalmic medicinal product is being used, the medicines must be administered at least 5 minutes apart. Eye ointments should be administered last.

4.6 Pregnancy and lactation:

Fertility:

Studies have not been performed in humans to evaluate the effect of topical administration of ciprofloxacin on fertility. Oral administration in animals does not indicate direct harmful effects with respect to fertility.

Pregnancy:

There are no adequate data from the use of CEPROLEN EYE/EAR DROPS (Ciprofloxacin Hydrochloride Solution) in pregnant woman. Animal studies do not indicate direct harmful effects with respect to reproductive toxicity. Systemic exposure to ciprofloxacin after topical use is expected to be low.

As a precautionary measure, it is preferable to avoid the use of CEPROLEN EYE/EAR DROPS (Ciprofloxacin Hydrochloride Solution) during pregnancy, unless the therapeutic benefit is expected to outweigh the potential risk to the fetus.

Breastfeeding:

Orally administered ciprofloxacin is excreted in the human milk. It is unknown whether ciprofloxacin is excreted in human breast milk following topical ocular or otic administration. A risk to the suckling child cannot be excluded. Therefore, caution should be exercised when CEPROLEN EYE/EAR DROPS (Ciprofloxacin Hydrochloride Solution) is administered to nursing women.

4.7 Effects on ability to drive and use machines:

This product has no or negligible influence on the ability to drive or use machines. Temporarily blurred vision or other visual disturbances may affect the ability to drive or use machines. If transient blurred vision occurs upon instillation, the patient must wait until the vision clears before driving or using machinery.

4.8 Undesirable effects:

Mild transient smarting & conjunctival congestion.

4.9 Overdose:

The limited holding capacity of the ear canal for topical otic products practically precludes overdosing via the ototopical route. However, oral ingestion of CEPROLEN EYE/EAR DROPS (Ciprofloxacin Hydrochloride Solution) resulting in overdose or long-term ototopical therapy may produce suppression of the Hypothalamic-Pituitary-Adrenal (HPA) Axis. Although decreases in paediatric growth velocity and/or suppression of cortisol plasma concentrations may be more pronounced after substantial overdose or prolonged treatment (e.g. several months) with CEPROLEN EYE/EAR DROPS (Ciprofloxacin Hydrochloride Solution), the effect is expected to be transient (days to weeks) and easily reversible with no long-term sequelae.

Treatment of acute overdosage is generally by supportive and systemic therapy, and may initially include emesis and gastric lavage.

5. Pharmacological properties:

5.1 Pharmacodynamic properties:

Pharmacotherapeutic Group – Ophthalmologicals, Other Antiinfectives.

ATC Code: S01AX13.

Mechanism of Action:

Ciprofloxacin Hydrochloride is a fluoroquinolone antibaderial agent with a wide spectrum of activity including *Enterobacteriaceae, Pseudomonasbaeruginosa, Haemophilus, and Neisseria spp* and also against *staphylococci* and some other gram positive bacteria. Ciprofloxacin is bactericidal and acts by inhibiting the a subunit of DNA gyrase (topisomerase) which is essential in the reproduction of baderial DNA. This leads to disruption of DNA structure and the death of the bacteria. It has a broader spectrum of activity and is one of the most active of the fluoroquinolones.

Benzalkonium Chloride is a quarternary ammonium compound with antiseptic properties. It has bactericidal activity against Gram positive and at a higher concentration against some Gram negative bacteria. It has variable antifungal activity and is also effective against some viruses.

5.2 Pharmacokinetic properties:

CEPROLEN EYE/EAR DROPS (Ciprofloxacin Hydrochloride Solution) is rapidly absorbed into the eye following topical ocular administration. Systemic levels are low following topical administration. Plasma levels of ciprofloxacin in human subjects following 2 drops of 0.3% ciprofloxacin solution every 2 hours for two days and then every four hours for 5 days ranged from non-quantifiable (<1.0 ng/mL) to 4.7 ng/mL. The mean peak ciprofloxacin plasma level obtained in this study is approximately 450-fold less than that seen following a single oral dose of 250 mg ciprofloxacin. The systemic pharmacokinetic properties of ciprofloxacin have been well studied. Ciprofloxacin widely distributes to tissues of the body. The apparent volume of distribution at steady state is 1.7 to 5.0 l/kg. Serum protein binding is 20-40%. The

half-life of ciprofloxacin in serum is 3-5 hours. Both ciprofloxacin and its four primary metabolites are excreted in urine and faeces. Renal clearance accounts for approximately two-thirds of the total serum clearance with biliary and faecal routes accounting for the remaining percentages. In patients with impaired renal function, the elimination half-life of ciprofloxacin is only moderately increased due to extrarenal routes of elimination. Similarly, in patients with severely reduced liver function the elimination half-life is only slightly longer.
There are no pharmacokinetic data available in respect of use in children.

5.3 Preclinical safety data:

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, and carcinogenic potential. Non-clinical developmental toxicity was observed only at exposures considered sufficiently in excess of the maximum human exposure, indicating little relevance to clinical use.

6. Pharmaceutical particulars:

6.1 List of excipients:

- Disodium Edetate
- Boric Acid
- Benzalkonium Chloride Solution
- Water for Injection

6.2 Incompatibilities:

Incompatible with alkaline solutions.

6.3 Shelf life:

24 Months.

6.4 Special precautions for storage:

Store away from light.

6.5 Nature and contents of container:

Gamma sterilized translucent LDPE bottle with natural LDPE nozzle and White HDPE cap.

6.6 Special precautions for disposal and other handling:

Do not use the solution if tamper evident ring of cap is broken or missing.
Use the solution within one month after opening the vial.

7. Marketing Authorization Holder:
INDOCO REMEDIES LTD.
166, C.S.T. Road,
Mumbai 400 098, INDIA.

8. Marketing Authorization Number(s):
05507/07284/REN/2020

9. Date of First Authorization/Renewal of the Authorization:
24.07.2021

10. Date of Revision of the Text:
25.08.2021