SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product:

Ciprocin ophthalmic solution

2. Qualitative and quantitative composition:

Each 1 ml or 1 g contains:

Ciprofloxacin (as hydrochloride) ..... 3 mg

3. Pharmaceutical form:

Ciprocin Sterile ophthalmic solution: A clear to slightly yellow solution.

Ciprocin Sterile ophthalmic ointment: A homogenous,spreadable,yellowish white unctuous semisolid preparation .

4. Clinical particulars:

4.1 Therapeutic indications:

Adults, newborn infants (0-27 days), infants and toddlers (28 days to 23 months), children (2-11 years) and adolescents (12 – 16 years)

- CIPROCIN is indicated for the treatment of corneal ulcers and superficial infections of the eye and adnexa caused by susceptible strains of bacteria.

Consideration should be given to official guidance on the appropriate use of antibacterial agents.

4.2 Posology and method of administration

Adults, newborn infants (0-27 days), infants and toddlers (28 days to 23 months), children (2-11 years) and adolescents (12 – 16 years)

Corneal Ulcers:

CIPROCIN must be administered in the following intervals, even during night time:

On the first day, instill 2 drops into the affected eye every 15 minutes for the first six hours and then 2 drops into the affected eye every 30 minutes for the remainder of the day.

On the second day, instill 2 drops in the affected eye hourly.

On the third through the fourteenth day, place two drops in the affected eye every 4 hours. If the patient needs to be treated longer than 14 days, the dosing regimen is at the discretion of the attending physician.

Children:

The safety and efficacy of CIPROCIN in children under the age of 1 year has not been established. The dosage in children above the age of 1 year is the same as for adults.

Ointment:

Apply a 1/2" ribbon into the conjunctival sac three times a day on the first two days, then apply a 1/2" ribbon two times a day for the next five days.

4.3 Contraindications:

Hypersensitivity to the active substance or to any of the recipients.

Hypersensitivity to quinolones.

4.4 Special warnings and precautions for use:

The clinical experience in children less than one year old, particularly in neonates is very limited. The use of CIPROCIN in neonates with ophthalmia neonatorum of gonococcal or chalamydial origin is not recommended as it has not been evaluated in such patients. Neonates with ophthalmia neonatorum should receive appropriate treatment for their condition.

When using CIPROCIN one should take into account the risk of rhinopharyngeal passage which can contribute to the occurrence and the diffusion of bacterial resistance.

Serious and occasionally fatal hypersensitivity (anaphylactic) reactions, some following the first dose, were observed in patients receiving treatment based on systematically administered quinolones. Some reactions were accompanied by cardiovascular collapse, loss of consciousness, tingling, pharyngeal or facial oedema, dyspnea, urticaria and itching. Only a few patients had a history of hypersensitivity reactions. Serious anaphylactic reactions require immediate emergency treatment with epinephrine and other resuscitation measures, including oxygen, intravenous fluids, intravenous antihistamines, corticosteroids, pressor amines and airway management, as clinically indicated.

Ciprofloxacin should be discontinued at the first appearance of skin rash or any other sign of hypersensitivity.

As with all antibacterial preparations prolonged use may lead to overgrowth of non-susceptible bacterial strains or fungi. If superinfection occurs, appropriate therapy should be initiated.

During therapy, soft contact lenses should not be worn.

Ophthalmic ointments may retard corneal healing and cause visual blurring.

Do not touch tip to any surface as this may contaminate the drug.

Do not use the product if the imprinted carton seals have been damaged, or removed.

4.5 Interaction with other medicinal products:

Specific drug interaction studies have not been conducted with ophthalmic ciprofloxacin. However, the systemic administration of some quinolones has been shown to elevate plasma concentrations of theophylline, to interfere with

the metabolism of caffeine, and to enhance the effect of the oral anticoagulant, warfarin, and its derivatives. Transient elevation in serum creatinine has been reported in patients receiving cyclosporine concomitantly with systemic ciprofloxacin.

4.6 pregnancy and lactation:

As there are no controlled studies in pregnant women CIPROCIN should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus.

Orally administered ciprofloxacin is excreted in the human milk. Excretion of ciprofloxacin into human milk following topical ophthalmic administration has not been investigated. Therefore, caution should be exercised when CIPROCIN is administered to nursing mothers.

4.7 Effects on ability to drive and use machines:

As there are no controlled studies in pregnant women CIPROCIN should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus.

Orally administered ciprofloxacin is excreted in the human milk. Excretion of ciprofloxacin into human milk following topical ophthalmic administration has not been investigated. Therefore, caution should be exercised when CIPROCIN is administered to nursing mothers.

Effects on ability to drive and use machines:

If your sight is affected in any way following use of CIPROCIN you should not drive or operate machinery.

4.8 Undesirable effects:

Local burning and ocular discomfort may occur as well as itching, foreign body sensation, lid margin crusting, crystals/scales, conjunctival hyperaemia and bad taste following instillation. Additionally, corneal staining, keratopathy/keratitis, allergic reactions, lid oedema, tearing, photophobia, corneal infiltrates, nausea and decreased vision, application site pain, ear pruritus, fungal ear superinfection, headache have been reported.

Hypersensitivity reactions cannot be excluded.

In patients with corneal ulcer and frequent administration of the drug, white precipitates have been observed which resolved after continuous application of CIPROCIN. The precipitate does not preclude the continued use of CIPROCIN nor does it adversely affect the clinical course of the ulcer or the visual outcome. The onset of the precipitate was within 24 hours to 7 days after starting therapy. Resolution of the precipitate varied from immediately to 13 days after therapy commencing.

With locally applied fluoroquinolones (generalized) rash, toxic epidermolysis, dermatitis exfoliative, Stevens-Johnson syndrome and urticaria occur very rarely.

In isolated cases blurred vision, decreased visual acuity and medication residue have been observed with ophthalmic ciprofloxacin.

Paediatric population:

Safety and effectiveness of CIPROCIN were determined in children between the ages of 0 and 12 years of age. No serious adverse drug reaction was reported in this group of patients.

Reporting of suspected adverse reactions

Health care professionals are asked to report any suspected adverse reactions via the https://pv.pharmacyboardkenya.org

4.9 Overdose:

A topical overdose of CIPROCIN may be flushed from the eye(s) with warm tap water.

5. Pharmacological properties:

5.1 Pharmacodynamic properties:

Pharmacotherapeutic Group: Ophtalmogicals, Other Anti-infectives

Ciprofloxacin has cidal and inhibitory activities against bacteria which result from an interference with DNA gyrase, an enzyme needed by the bacterium for the synthesis of DNA. Thus, vital information from the bacterial chromosomes cannot be transcribed, which causes a break-down of bacterial metabolism.

Ciprofloxacin has a very high in vitro activity against almost all gram negative microorganisms including Pseudomonas aeruginosa. It is also effective against gram positive bacteria, such as Staphylococci and Streptococci. Anaerobes are in general less susceptible.

Resistance development against ciprofloxacin occurs infrequently. A plasmid-mediated bacterial resistance does not appear to occur with the fluoroquinolone class of antibiotics.

5.2 Pharmacokinetic properties:

After topical ocular administration, ciprofloxacin is also absorbed systemically. Plasma levels in volunteers ranged from nonquantifiable to 4.7 ng/mL (some 450-fold less than levels observed following sample 250 mg oral administration).

There are no pharmacokinetic data available in respect of use in children.

5.3 Preclinical safety data

None known

6. Pharmaceutical particulars:

6.1 List of excipients:

Drops: Benzalkonium Chloride, disodium edentate, mannitol, acetic Acid glacial, sodium acetate anhydrous, Sodium hydroxide or Hydrochloric acid, water for injection.

Ointment: Anhydrous lanolin, chlorobutanol, Yellow soft paraffin.

6.2 Incompatibilities:

None known.

6.3 Shelf life:

Ciprocin eye drops: 3 years.

Ciprocin Sterile ophthalmic ointment: 2 years.

6.4 Special precautions for storage:

Ciprocin eye drops: Store at temperature not exceeding 30°C.

Use for 28 days after opening and store at room temperature.

Store below 30°C.

6.5 Nature and contents of container:

CIPROCIN eye/ear drops: Plastic dropper bottles, 5 ml each.

CIPROCIN Sterile ophthalmic ointment: Ophthalmic tubes, 5 gm each.

6.6 Special precautions for disposal and other handling:

No special requirements

7. MARKETING AUTHORISATION HOLDER

Egyptian International Pharmaceutical Industries Co. (EIPICO)

8. MARKETING AUTHORISATION NUMBER(S)

H2025/CTD12081/25264

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

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