1. Name of the medicinal product

Ciflaxin Sterile Eye/Ear Drops

2. Qualitative and quantitative composition

Each ml contains 3mgCiprofloxacininthe form of Ciprofloxacin hydrochloride

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Sterile Eye /Ear Drops

4.1 Therapeutic indications

Ciflaxin® Sterile Eye/Ear Drops is indicated for treatment of Bacterial conjunctivitis, Blepharitis, Bacteria, Keratitis, Corneal ulcer, Otitis externa.

4.2 Posology and method of administration

Posology

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

Method of Administration

Ophthalmic

Instill one or two drops intotheconjunctival sac(s) every two hours for two days and one or two drops every four hours for 5days In case of bacterial conjunctivitis. In case of Cornea Ulcers, instil 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 rest of the day. Two drops everyhours on second day and two drops should be placed into the affected eye every four hours from the third to the fourteenth day.Two drops to be placed Inthe affected ear every four hours.

Superficial Ocular Infection:

The usual dose is one or two drops in the affected eye(s) four times a day. In severe infections, the dosage for the first two days may be one or two drops every two hours during waking hours.

For either indication a maximum duration of therapy of 21 days is recommended.

The dosage in children above the age of 1 year is the same as for adults.

4.3 Contraindications

History of Hypersensitivity toCiprofloxacin or any of its components or their quinolones.

4.4 Special warnings and precautions for use

Talk to your doctor or pharmacist before using Ciflaxin Sterile Eye /Ear If:

- After cap is removed, if tamper evident snap collar is loose, remove before using product.
- The clinical experience in children less than one year old, particularly in neonates is very limited. The use of Ciflaxin Eye/Ear drops 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 CILOXAN eye drops 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, dyspnoea, urticaria and itching. Only a few patients had a history of hypersensitivity reactions (see section 4.8).
- Serious acute hypersensitivity reactions to ciprofloxacin may require immediate emergency treatment. Oxygen and airway management should be administered where clinically indicated.
- Ciflaxin 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.
- Tendon inflammation and rupture may occur with systemic fluoroquinolone therapy including ciprofloxacin, particularly in elderly patients and those treated concurrently with corticosteroids.

Therefore, treatment with CILOXAN Eye Drops should be discontinued at the first sign of tendon inflammation (see section 4.8).

- In patients with corneal ulcer and frequent administration of CILOXAN Eye Drops, white topical ocular precipitates (medication residue) have been observed which resolved after continued application of CILOXAN Eye Drops. The precipitate does not preclude the continued application of Ciflaxin Eye Drops nor does it adversely affect the clinical course of the recovery process. 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.

- Contact lens wear is not recommended during treatment of an ocular infection. Therefore, patients should be advised not to wear contact lenses during treatment with Ciflaxin eye/ear drops.

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.

4.6 Fertility, 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 CILOXAN 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 CILOXAN 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 CILOXAN 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

Adverse In clinical trials, the most frequently reported adverse drug reactions were ocular discomfort, dysgeusia and corneal deposits occurring approximately in 6%, 3% and 3% of patients respectively.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the risk/benefit balance of the medicinal product.

4.9 Overdose

A topical overdose of CILOXAN may be rinsed out from the eye(s) with lukewarm tap water. Due to the characteristics of this preparation no toxic effects are to be expected with an ocular overdose of this product, or in the event of accidental ingestion of the contents of one bottle.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic Group: Ophthalmologicals, and other Anti-infectives

ATC Code: S01AE03

Mechanism of action

CILOXAN eye drops, solution contains the fluoroquinolone ciprofloxacin. The cidal and inhibitory activity of ciprofloxacin against bacteria results from an interference with the DNA gyrase, an enzyme needed by the bacterium for the synthesis of DNA. Thus the vital information from the bacterial chromosomes cannot be transcribed which causes a breakdown of the bacterial metabolism. Ciprofloxacin has in vitro activity against a wide range of Gram-positive and Gram-negative bacteria.

5.2 Pharmacokinetic properties

Absorption

CIFLAXIN Eye/Eardrops, 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.

Distribution

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.

Metabolism

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.

Elimination

In patients with impaired renal function, the elimination half-life of ciprofloxacin is only moderately increased due to extra renal routes of elimination. Similarly, in patients with severely reduced liver function the elimination half-life is only slightly longer.

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

CiprofloxacinHcl

Sodium Chloride

Disodium Edetate

Benzalkonium Chloride,

Sodium Acetate

Acetic Acid

6.2 Incompatibilities

None known.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store below 30°C. Protect from light and moisture.

6.5 Nature and contents of container

A round sterile transparentlupoleneplastic eye drops bottle with white screwed capin folding box board.

Pack size: 5ml

6.6 Special precautions for disposal and other handling

Patients should be advised to wash their hands after applying Ciflaxin® Eye/Ear dropsunless it is the hands that are being treated.

7.0 APPLICANT/MANUFACTURER

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