SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT
CIPROFLOXACIN EYE/EARS DROPS

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Composition:
Ciprofloxacin Hydrochloride USP
eq. to Ciprofloxacin 0.3% w/v
Benzalkonium Chloride NF 0.01% w/v

a3. PHARMACEUTICAL FORM
Ophthalmic solution

4. CLINICAL PARTICULARS
4.1 Therapeutic Indications
Treatment of superficial ocular infections:
Conjunctivitis, keratitis, keratoconjunctivitis, corneal ulcers, blepharitis, blepharo-conjunctivitis, acute melbomlanitis and dacryocystitis caused by strains susceptible to ciprofloxacin.
Prophylaxis: Infections due to Neisseria gonorrhoea or Chlamydia trachomatis Prevention of ocular infections after removal of a corneal or conjunctival foreign body after damage from chemical or physical agents, before and after ocular sugery.

EAR:
Otitis externa, acute otitis media, chronic suppurative otitis media.
Prophylaxis in otic surgeries such as mastoid surgery.

4.2 Dosage and administration:
Do not torch the nozzle tip to avoid contermination of the solution.
EYE:
Acute infections:
One or two drops every 15 to 30 minutes, initially reducing the frequency of instillation with control of infection.
Moderate infections:
One to two drops, two to six times daily or as often as needed.
Acute and chronic trachoma:
Two drops in each eye, two to four times daily for one to two month or longer.
EAR:
For all infections two to three drops every two to three the frequency of instillation with control of infections

4.3 Contraindications:

Hypersensitivity to quinolone group of antibacterials or any of the components of the formulation.

4.4 Special Warnings and Precautions for Use

i) If irritation persists or increases, discontinue the use and consult physician.
ii) Do not touch dropper tip or other dispensing tip to any surface since this may contaminate solutions

"NOT FOR INJECTION" FOR EXTERNAL USE ONLY

Prolonged use may result in overgrowth of nonsusceptible organisms, including fungi. If superinfection occurs, appropriate measures should be initiated. Serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been reported in patients receiving systemic quinolone therapy. Ciprofloxacin Ophthalmic Solution should be discontinued at the first appearance of a skin rash or any sign of other hypersensitivity reaction. The concurrent use of oral quinolones and theophylline may lead to elevated plasma concentrations of theophylline and prolongation of its elimination half-life. Transient increases in serum creatinine concentrations have been observed in patients receiving cyclosporin concomitantly with systemic ciprofloxacin. As the possibility of adverse effects on the corneal permeability and the danger of disruption of the corneal epithelium with prolonged or repeated usage of benzalkonium chloride preserved ophthalmological preparations cannot be excluded, regular ophthalmological examination is required. Caution should be exercised in the use of benzalkonium chloride preserved topical medication over an extended period in patients with extensive ocular surface disease.

4.5 Interaction with other Medicinal products and other forms of Interaction

Specific drug interaction studies have not been conducted with ophthalmic ciprofloxacin.

4.6 Fertility, pregnancy and lactation

PREGNANCY

Safety in pregnant women has not been established.

NURSING MOTHERS

It is not known whether topically applied ciprofloxacin is secreted in breast milk, however caution should be exercised when administering to a nursing mother.

PAEDIATRIC USE

Safety and effectiveness in children under the age of 12 have not been established. There is no evidence that the ophthalmic dosage form has any effect on the weight bearing joints.

Pharmaceutical Precautions

Use the solution within one month after opening the vial.

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

Local burning and ocular discomfort may occur as well as itching and foreign body sensation, lid margin crusting, crystals/scales, conjunctival hyperaemia and bad taste following instillation. Moreover, corneal stinging, keratopathy/keratitis, allergic reactions, lid oedema, tearing, photophobia, corneal infiltrates, nausea and decreased vision may occur. Hypersensitivity reactions cannot be excluded. In patients with corneal ulcer and frequent administration of the drug, a white precipitate may be observed which resolves spontaneously with continued application of Ciprofloxacin Ophthalmic Solution. The precipitate does not preclude continued use of the solution nor does it adversely affect the clinical course of the ulcer or the visual outcome. Safety during pregnancy and lactation have not been established.

4.9 Overdose

A topical overdose of Ciprolfoxacin Ophthalmic Solution may be flushed from the eye(s) with warm tap water. Treatment should be symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

ATC classification
Pharmacotherapeutic group: Ophthalmologicals, Other Antiinfectives
ATC code : S01A X13

Mode of action:

Ciprofloxacin is a broad-spectrum water-soluble fluoroquinolone antibacterial. It has cidal and inhibitory activities against bacteria which result from an interference with the DNA gyrase, an enzyme required by the bacterium for the synthesis of DNA. Thus the vital information from the bacterial chromosomes cannot be transcribed any longer which causes a break-down in the bacterial metabolism. Ciprofloxacin has an in vitro activity against a wide range of Gram negative micro-organisms including Pseudomonas aeruginosa and Serratia marcescens. It is also effective in vitro against Gram positive bacteria such as Staphylococci and Streptococci including Staphyloccus aureus (including methicillin-susceptible and methicillin-resistant strains); Staphylococcus epidermidis, Streptococcus pneumonia and Streptococcus (viridans group).

Microbiology: Ciprofloxacin has *in vitro* activity against wide range of gram-negative and gram-positive organisms. The bactericidal action of ciprofloxacin results from interference with the enzyme DNA gyrase which is needed for the synthesis of bacterial DNA.

Gram-Positive:
Pseudomonas aeruginosa
Serratia marcescens

Ciprofloxacin has been shown to be active *in vitro* against most strain of the following organisms; however, the clinical significance of these data is unknown:

Gram-Positive:
Enterococcus faecalis (many strains are only moderately susceptible)
Staphylococcus haemolyticu

Staphylococcus hominis
Staphylococcus saprophyticus
Streptococcus pyogenes

Gram-Negative:

Acinetobacter calcoaceticus	*Escherichia coli*	*Proteus mirabilis*
Subsp.Anitratus	*Haemophilus ducreyi*	*Proteus vulgaris*
Aeromonas caviae	*Haemophilus influenza*	*Providencia rettgeri*
Aeromonas hydrophila	*Haemophilus parainfluenzae*	*Providencia stuatii*
Brucella melitensis	*kiebsiella pneumoniae*	*Salmonella enteritidis*
Campylobacter coli	*Klebsiella oxytoca*	*Salmonella typhi*
Campylobacter jujuni	*Legionella pneumophila*	*Shigella sonneii*
Citrobacter freundii	*Moraxella morganii*	*Vibrio cholera*
Edwarsiella tarda	*Neisseria gonorrheae*	*Vibro parahaemolyticus*
Enterobacter aerogenes	*Neisseria meningitides*	*Vibro vulnificus*
Enterobacter cloacae	*Pasteurella multicoda*	*Yersinia enterocolitica*

5.2. Pharmacokinetic properties

Ciprofloxacin is absorbed systemically after topical ocular administration. Plasma levels range from nonquantifiable to 4,7 ng/mL (some 450-fold less than levels observed following simple 250 mg oral administration)

5.3 Preclinical safety data

Reproduction studies have been performed in rats and mice at doses up to six times the usual daily human oral and dose and have revealed no evidence of impaired fertility or harm to the fetus due to ciprofloxacin. After intravenous administration at doses up to 20mg/kg, no material toxicity was produced and no embryo toxicity was observed.

Carcinogenesis, Mutagenesis, Impairment of Fertility:

Long term carcinogenicity studies in mice and rats have been completed, after daily oral dosing for up to two years, there is no evidence that ciprofloxacin had any carcinogenic or tumorigenic effects in these species.

6. PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS:

Following excipients are used in the formulation of CIPROFLOXACIN EYE/EAR DROPS 0.3%w/v:
Benzalkonium Chloride
Sodium Chloride
Disodium EDTA
Water for Injection

6.2 Shelf Life

24 Months

6.3 Special Precautions for Storage
Store in cool and dark place.

Keep out of reach of children.
FOR EXTERNALUSE ONLY. NOT FOR INJECTION.

6.4 Nature and Contents of Container
10 ml LDPE white plastic bottle with cap.
Pack size: One bottle to be packed in a carton along with pack insert.

6.5 Special Precautions for Disposal and Other Handling
For Otic/ophthalmic use only.
Use the solution within one month after opening the bottle.
Shake well before use.
Do not touch the nozzle tip to avoid contamination of the solution.

7. MARKETING AUTHORISATION HOLDER

MARKETED BY:
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