SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT
Ciprofloxacin eye/ear drops 0.3%w/v

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each ml contains:
Ciprofloxacin Hydrochloride USP
Eq. to Ciprofloxacin 0.3% w/v
Benzalkonium Chloride NF…..0.01%w/v
(As Preservative)

3. PHARMACEUTICAL FORM
Eye / Ear Drop.
A clear colourless solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

In Adults and Children (age ≥1 year)

EYE: Ciprofloxacin Eye/ Ear Drops 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.

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

4.2 Posology and method of administration
External Ocular Infection

Adults and Children (age ≥1 year): 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 2 days may be one or two drops every 2 hours during waking hours.

A maximum duration of therapy of 21 days is recommended.

Ears Infections

Adults and Children (age ≥1 year): For all infections, two to three drops every 2–3 hours initially, reducing the frequency of the instillation with control of infection.

4.3 Contraindications

Hypersensitivity to quinolones or any component of this medication.

4.4 Special warnings and precautions for use
General

NOT FOR INJECTION INTO THE EYE. FOR TOPICAL USE ONLY.

The clinical experience in children less than one year old, particularly in neonates is very limited. The use of Ciprofloxacin 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 Ciprofloxacin eye/ear 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, have been reported in patients receiving systemic quinolone therapy. 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.

Serious acute 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 eye/ear drops 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.

Remove contact lenses before using. During therapy, soft contact lenses should not be worn.

As with other antibacterial preparations, prolonged use of ciprofloxacin may result in overgrowth of non-susceptible organisms, including fungi. If super-infection occurs, appropriate therapy should be initiated. Whenever clinical judgement dictates, the patient should be examined with the aid of magnification, such as slit-lamp biomicroscopy and, where appropriate, fluorescein staining.

4.5 Interaction with other medicinal products and other forms of interaction

Specific drug interaction studies have not been conducted with ciprofloxacin eye/ear drops. However, the systemic administration of some quinolones has been shown to elevate plasma concentrations of theophylline, interfere with the metabolism of caffeine, enhance the effects of the oral anticoagulant, warfarin and its derivatives, and has been associated with transient elevations in serum creatinine in patients receiving cyclosporine concomitantly.

4.6 Fertility, pregnancy and lactation

There are no adequate data from the use of Ciprofloxacin Eye/ Ear Drops 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 Ciprofloxacin Eye/ Ear Drops during pregnancy, unless the therapeutic benefit is expected to outweigh the potential risk to the fetus.
It is unknown whether ciprofloxacin is excreted in human breast milk following topical ocular or otic administration.

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

The adverse reactions listed below are classified according to the following convention: very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1,000 to <1/100), rare (≥1/10,000 to <1/1,000), very rare (<1/10,000), or not known (cannot be estimated from the available data). Within each frequency-grouping, adverse reactions are presented in order of decreasing seriousness. The adverse reactions have been observed during clinical trials and postmarketing experience.

The following undesirable effects were reported in association with the use of ciprofloxacin eye/ear drops:

System Organ Classification	MedDRA Preferred Term (v. 15.1)
Infections and infestations	Rare: hordeolum, rhinitis
Immune system disorders	Rare: hypersensitivity
Nervous system disorders	Common: dysgeusia Uncommon: headache Rare: dizziness
Eye disorders	Common: corneal deposits, ocular discomfort, ocular hyperaemia Uncommon: keratopathy, corneal infiltrates, corneal staining, photophobia, visual acuity reduced, eyelid oedema, blurred vision, eye pain, dry eye, eye swelling, eye pruritus, foreign body sensation in eyes, lacrimation increased, eye discharge, eyelid margin crusting, eyelid exfoliation, conjunctival oedema, erythema of eyelid Rare: ocular toxicity, punctate keratitis, keratitis, conjunctivitis, corneal disorder, corneal epithelium defect, diplopia, hypoaesthesia eye, asthenopia, eye irritation, eye inflammation, conjunctival hyperaemia
Ear and labyrinth disorders	Rare: ear pain
Respiratory, thoracic and mediastinal disorders	Rare: paranasal sinus hypersecretion, rhinitis.
Gastrointestinal disorders	Uncommon: nausea Rare: diarrhoea, abdominal pain
Skin and subcutaneous tissue disorders	Rare: dermatitis
General disorders and administration site conditions	Rare: drug intolerance
Musculoskeletal and connective tissue disorders	Not known: tendon disorder
Investigations	Rare: laboratory test abnormal

4.9 Overdose

A topical overdose of ciprofloxacin eye drops may be flushed 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

Mechanism of Action
The bactericidal action of ciprofloxacin results from inhibition of the enzyme, DNA gyrase, which is required for the synthesis of bacterial DNA.

5.1 Pharmacodynamic properties

Pharmacotherapeutic Group – Ophthalmologicals, Other Anti-infectives.
ATC Code: S01A X13.
Ciprofloxacin eye/ear drops contain the fluoroquinolone, ciprofloxacin. The bactericidal 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.

Mechanism of Resistance
Fluoroquinolone resistance, particularly ciprofloxacin, requires significant genetic changes in one or more of five major bacterial mechanisms: a) enzymes for DNA synthesis, b) protecting proteins, c) cell permeability, d) drug efflux, or e) plasmid-mediated aminoglycoside 6'-N-acetyltransferase, AAC (6')-Ib.
Fluoroquinolones, including ciprofloxacin, differ in chemical structure and mode of action from aminoglycosides, β-lactam antibiotics, macrolides, tetracyclines, sulphonamides, trimethoprim, and chloramphenicol. Therefore, organisms resistant to these drugs may be susceptible to ciprofloxacin.

5.2 Pharmacokinetic properties

Ciprofloxacin in Ciprofloxacin eye/ear drops 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 two drops of 0.3% ciprofloxacin solution every 2 hours for 2 days and then every 4 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 1.7–5.0 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 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

Not known

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Benzalkonium Chloride, Sodium Chloride, Disodium EDTA, Water for Injection

6.2 Incompatibilities
Not known

6.3 Shelf life
24 Months

6.4 Special precautions for storage

Store below 30°C. Protect from light.
Keep out of reach of children.

6.5 Nature and contents of container and special equipment for use, administration or implantation
5 ML LDPE Bottle.

6.6 Special precautions for disposal and other handling

None.

7. MARKETING AUTHORISATION HOLDER

Ciron Drugs & Pharmaceuticals Pvt. Ltd.
C- 1101 /1102, Lotus Corporate Park, Graham Firth Steel Compound,
Jay Coach Junction, Western Express Highway, Goregaon (East)
Mumbai- 400 063, India.

8. MARKETING AUTHORISATION NUMBER(S)

06484/08102/REN/2021

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21.11.2017
Date of first Renewal: 12.08.2021

10. DATE OF REVISION OF THE TEXT

14/07/2023

11. Reference

https://ciplamed-library.com/content/ciplox-eyeear-drops