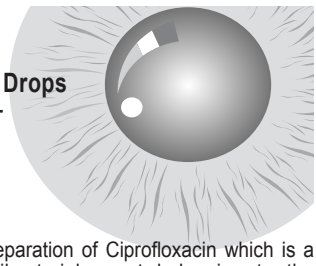
Ciprocin® Eye/Ear Drops



Ciprofloxacin USP 0.3%
Sterile Solution

Ciprocin® Eye/Ear Drops is sterile preparation of Ciprofloxacin which is a potent, broad-spectrum, synthetic antibacterial agent belonging to the fluoroquinolone group. It exerts bactericidal effect by inhibiting DNA gyrase, an essential enzyme involved in DNA replication.

COMPOSITION
Each ml contains Ciprofloxacin hydrochloride USP equivalent to Ciprofloxacin 3 mg.

INDICATION
Eye
Ciprocin® Eye/Ear Drops is indicated for the treatment of infections caused by susceptible strains of the designated microorganisms in the conditions listed below:
Corneal Ulcers: *Pseudomonas aeruginosa, Serratia marcescens, Staphylococcus aureus, Staphylococcus epidermidis, Streptococcus pneumoniae.*
Bacterial Conjunctivitis: *Haemophilus influenzae, Staphylococcus aureus, Staphylococcus epidermidis, Streptococcus pneumoniae.*
It is also indicated in the treatment of keratitis, kerato-conjunctivitis, blepharitis, blepharo-conjunctivitis, dacryocistitis, prophylaxis of ocular infections due to *Neisseria gonorrhea* or *Chlamydia trachomatis,* prevention of ocular infections after removal of a corneal or physical agent before or after ocular surgery.
Ear
Otitis externa, acute otitis media, chronic suppurative otitis media. Prophylaxis in otic surgeries such as mastoid surgery.

DOSAGE AND ADMINISTRATION
Eye
Corneal Ulcers: The recommended dosage regimen for the treatment of corneal ulcers is two drops into the affected eye every 15 minutes for the first 6 hours and then two drops into the affected eye every 30 minutes for the remainder of the first 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 four hours. Treatment may be continued after 14 days if corneal re-epithelization has not been occurred.
Bacterial Conjunctivitis: The recommended dosage regimen for the treatment of bacterial conjunctivitis is one or two drops instilled into the conjunctival sac(s) every two hours while awake for two days and one or two drops every four hours while awake for the next five days.
Ear
For all infections, 2-3 drops every 2-3 hours initially, reducing the frequency of the instillation with control of infection. Treatment should be continued at least 7 days.

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

PRECAUTION
Prolonged ocular use of Ciprofloxacin may result in overgrowth of non-susceptible organisms, including fungi. Ciprofloxacin should be discontinued at the first appearance of a skin rash or any other sign of hypersensitivity reaction.

WARNING
Not for injection into the eyes. Contact lenses should not be worn in presence of infectious eye diseases.

SIDE EFFECTS
Local burning or discomfort, itching, foreign body sensation, crystalline precipitates, lid margin crusting, conjunctival hyperemia and a bad taste following administration. Photophobia and nausea may be reported.

DRUG INTERACTION
Specific drug interaction studies have not been conducted with Ciprofloxacin.

PREGNANCY
Safety in pregnant women has not been established.

NURSING MOTHER
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 1 year of age have not been established.

OVERDOSAGE
A topical overdose may be flushed from the eye/s with warm tap water.

STORAGE
Store below 30^0C in a cool and dry place protected from light. Keep out of reach of children. Do not touch the dropper tip to surfaces since this may contaminate the solution. Do not use after 30 days of first opening.

HOW SUPPLIED
Ciprocin® Eye/ Ear drops: Each plastic dropper bottle contains 5 ml of Ciprofloxacin USP 0.3% sterile solution.

Manufactured by :

SQUARE
PHARMACEUTICALS LTD.
BANGLADESH