Please read this leaflet carefully before you start to use Ciprocin Eye Drops U.S.P.(Ciprofloxacin Hydrochloride)

CIPROCIN

Eye Drops

Composition

Ciprofloxacin Hydrochloride U.S.P
equivalent to Ciprofloxacin 0.3%w/v
Benzalkonium chloride U.S.P(as preservative)..... 0.01%w/v
Aqueous vehicle..... q.s

PHARMACOLOGICAL PROPERTIES:

Clinical pharmacology Ciprofloxacin has in vitro activity against a 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.
Ciprofloxacin has been shown to be active against most strains of the following microorganisms both in vitro and in clinical infections
Gram-Positive: *Staphylococcus aureus, Staphylococcus epidermidis,Streptococcus pneumonia, Streptococcus* (Viridans Group)
Gram-Negative: *Haemophilus influenzae, Pseudomonas aeruginosa, Serratiamarcescens*
Other Organisms: *Chlamydia trachomatis* (only moderately susceptible) and *Mycobacterium tuberculosis* (only moderately susceptible). Most strains of *Pseudomonas cepacia* and some strains of *Pseudomonas maltophilia* are resistant to ciprofloxacin as are most anaerobic bacteria, including *Bacteroides fragilis* and *Clostridium difficile*. The minimal bactericidal concentration (MBC) generally does not exceed the minimal inhibitory concentration (MIC) by more than a factor of 2. Resistance to ciprofloxacin in vitro usually develops slowly (multiple-step mutation).
Ciprofloxacin does not cross-react with other antimicrobial agents such as beta-lactams or aminoglycosides; therefore, organisms resistant to these drugs may be susceptible to ciprofloxacin.

INDICATIONS :

CIPROCIN eye is indicated for the treatment of infections caused by susceptible strains of the designated microorganisms in the conditions listed below: Conjunctivitis: *Haemophilus influenza, Staphylococcus aureus, Staphylococcus epidermidis, Streptococcus pneumoniae* Corneal Ulcers: *Pseudomonas aeruginosa, Serratiamarcescens, Staphylococcus aureus, Staphylococcus epidermidis,Streptococcus pneumonia, Streptococcus* (Viridans Group).

DOSAGE:

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 six hours and then two drops into the affected eye every 30 minutes for the remainder of the first day. On the second day, instill two 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-epithelialization has not 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.

CONTRAINDICATION

CIPROCIN is contraindicated in persons with history of hypersensitivity to ciprofloxacin, any member of the quinolone class of antimicrobial agents, or any of the product components.

PRECAUTIONS

As with other antibacterial preparations, prolonged use of ciprofloxacin may result in over growth of non susceptible organisms, including fungi. If superinfection occurs, appropriate therapy should be initiated. Whenever clinical judgment dictates, the patient should be examined with the aid of magnification, such as slit lamp bio microscopy and, where appropriate, fluorescein staining. Ciprofloxacin should be discontinued at the first appearance of a skin rash or any other sign of hypersensitivity reaction.

Pregnancy:

Reproduction studies have been performed in rats and mice at doses up to six times the usual daily human oral dose and have revealed no evidence of impaired fertility or harm to the foetus due to ciprofloxacin. In rabbits, as with most antimicrobial agents, ciprofloxacin (30 and 100 mg/kg orally) produced gastrointestinal disturbances resulting in maternal weight loss and an increased incidence of abortion. No teratogenicity was observed at either dose. There are no adequate and well controlled studies in pregnant women.
CIPROCIN drops should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus.

Nursing Mothers:

It is not known whether topically applied ciprofloxacin is excreted in human milk. However, it is known that orally administered ciprofloxacin is excreted in the milk of lactating rats and oral ciprofloxacin has been reported in human breast milk after a single 500 mg dose. Caution should be exercised when CIPROCIN drop is administered to a nursing mother.

Pediatric Use:

Safety and effectiveness in pediatric patients below theage of 1 year have not been established. Although ciprofloxacin and other quinolones cause arthropathy in immature animals after oral administration, topical ocular administration of ciprofloxacin to immature animals did not cause any arthropathy and there is no evidence that the ophthalmic dosage form has any effect on the weight bearing joints.

DRUG INTERACTION

Drug interactions 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, 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.

SIDE EFFECTS:

The most frequently reported drug related was local burning or discomfort. In corneal ulcer studies with frequent administration of the drug, white crystalline precipitates were seen in approximately 17% of patients. Other side effects occurring in less than 10% of patients included lid margin crusting, crystals/scales, foreign body sensation, itching, conjunctival hyperemia and a bad taste following instillation. Additional events occurring in less than 1% of patients included corneal staining, keratopathy/keratitis, allergic reactions, lid edema, tearing, photophobia, corneal infiltrates, nausea and decreased vision.

PRESENTATION

Clear, colorless solution in sterile plastic dropper bottles of 10ml and 5ml enclosed in protective carton with leaflet.

SHELF LIFE

The manufacturing and expiry dates are indicated on the packaging.

STORAGE

Store below 30° C but do not freeze, protect from light.
Discard after the expiration date or one month after opening the bottle.
KEEP THE DROP OUT OF CHILDREN'S REACH.

DIRECTION FOR USE

Tighten the cap on the nozzle
The spike in the cap will pierce the tip of the vial.
Dispense drops with gentle pressure.
Replace the cap after every use.

WARNING

Ciprocin eye drops is for eye use only and not for injections or oral use.

1. If irritation persists or increases, discontinue the use and consult a doctor.
2. Do not touch the vial tip or other dispensing tip to any surface since this may contaminate the solution.
3. Use the solution within one month after opening the vial.

Wash your hands well before use.

For the Eye Drops:

1. Remove the outer cap.
2. Tilt the head back and pull the lower lid of the eye down to form a pocket.
3. Hold the container between the thumb and middle finger of the other hand, turn the container upside down near to the eye, and try not to touch the eye.
4. Apply enough pressure to the container to release one to two drops
5. Close the eye and keep it closed for one to two minutes
6. If you think you have missed the eye, then insert another drop.
7. Repeat in the other eye if you have been instructed to use this preparation in both eyes.
8. Replace the outer cap on the container, try not to touch the applicator tip with the fingers as you do so.
9. Wash your hands

For further information, please consult your pharmacist or doctor.

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