120mm

170mm

Ciproxol Sterile Eye Drops

(Ciprofloxacin HCl)

سیپروکسول جراثیم سے پاک آنکھوں کے قطرے

(سیپروفلوکساسین ایچ سی ایل)

COMPOSITION:
Each ml contains:
Ciprofloxacin (as hydrochloride).....3mg
(USP Specifications)

DESCRIPTION:
Ciprofloxacin is a synthetic antibiotic of the fluoroquinolone drug class considered to be a second-generation fluoroquinolone. It is a synthetic broad-spectrum antimicrobial agent that inhibits the supercoiling activity of bacterial DNA gyrase, halting DNA replication.

MODE OF ACTION:
The bactericidal action of ciprofloxacin results from inhibition of the enzymes topoisomerase II (DNA gyrase) and topoisomerase IV (both Type II topoisomerases), which are required for bacterial DNA replication, transcription, repair, and recombination.

INDICATIONS AND USAGE:
CIPROXOL is indicated for the treatment of infections caused by susceptible strains of the designated microorganisms in the conditions and patient populations listed below:
Corneal Ulcers caused by Pseudomonas aeruginosa, Serratia marcescens, Staphylococcus aureus,Staphylococcus epidermidis, Streptococcus pneumonia, Streptococcus (Viridans Group)
Conjunctivitis caused by Staphylococcus aureus, Staphylococcus epidermidi, Streptococcus pneumonaie.

DOSAGE AND ADMINISTRATION:
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. 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.

PHARMACOKINETICS:
A systemic absorption study was performed in which Ciprofloxacin was administered in each eye every two hours while awake for two days followed by every four hours while awake for an additional 5 days. The maximum reported plasma concentration of ciprofloxacin was less than 5 ng/ml. The mean concentration was usually less than 2.5 µg/ml.

WARNINGS:
FOR TOPICAL USE ONLY - NOT FOR INJECTION.
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 edema, dyspnea, urticaria and itching. Only a few patients had a history of hypersensivity reactions. Serious anaphylactic reactions require immediate emergency treatment with epinephrine and other resuscitation measures, including oxygen, intravenous fluids, intravenous antihistamines, corticosteroids, and airway management, as clinically indicated.
Remove contact lenses before using.

PRECAUTIONS:
General: As with other antibacterial preparations, prolonged use of ciprofloxacin may result in overgrowth 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.
In clinical studies of patients with bacterial corneal ulcer, a white crystalline precipitate located in the superficial portion of the corneal defect was observed in 35 (16.6%) of 210 patients. The onset of the precipitate was within 24 hours to 7 days after starting therapy in one patient, the precipitate was immediately irrigated out upon its appearance. In 17 patients, resolution of the precipitate was seen in 1 to 8 days (seven within the first 24-72 hours); in five patients, resolution was noted in 10-13 days. In nine patients, exact resolution days were unavailable; however, at follow-up examinations, 18-44 days after onset of the event, complete resolution of the precipitate was noted. In three patients, outcome information was unavailable. The precipitate did not preciude continued use of ciprofloxacin, nor did it adversely affect the clinical course of the ulcer or visual outcome.
Usage during Pregnancy: CIPROXOL Ophthalmic Solution should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
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 CIPROXOL Ophthalmic Solution is administered to a nursing mother.

ADVERSE REACTIONS:
The most frequently reported drug related adverse reaction 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 reactions 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.

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 have been associated with transient elevations in serum creatinine in patients receiving cyclosporine concomitantly.

CONTRAINDICATIONS:
A history of hypersensitivity to ciprofloxacin or any other component of the medication is a contraindication to its use. A history of hypersensitivity to other quinolones may also contraindicate the use of ciprofloxacin.

OVERDOSAGE:
A topical overdose of CIPROXOL Ophthalmic Solution may be flushed from the eye(s) with warm tap water.

STORAGE & INSTRUCTIONS:
Store between 15-25°C.
Protect from heat, sunlight, moisture and do not freeze.
Keep away from the reach of children.
Use within one month after first opening the bottle and discard the remaining portion.
Do not touch the dropper tip to any surface as this may contaminate the solution.
To be used on the prescription of a registered medical practitioner only.
For ophthalmic use only.

HOW SUPPLIED:
5ml sterile ophthalmic solution in plastic dropper bottle.

خوراک و ہدایات: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
دوا کو ۱۵۔۲۵ ڈگری سینٹی گریڈ درجہ حرارت کے درمیان رکھیں۔ دھوپ، گرمی، نمی اور منجمد ہونے سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔
پہلی دفعہ بوتل کھولنے کے بعد دوا کو ایک ماہ تک استعمال کریں۔
صرف مستند ڈاکٹر کے نسخے کے مطابق استعمال کریں۔

Manufactured by:
PHARMASOL
PRIVATE LIMITED
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* Sign. Client

* Sign. Marketing Deptt. Shannza

* Sign. Designer Shannza

* for Design, Text, Size, Color & Color Placement

* Sign. Head of Design Deptt. Shannza