QUINOCIP

EYE DROPS & EYE OINTMENT

(Ciprofloxacin 0.3%)

DESCRIPTION / COMPOSITION

Quinocip Eye Drops: Sterile ophthalmic solution containing ciprofloxacin 0.3% w/v, equivalent to 3 mg ciprofloxacin per mL. **Presentation:** 5 mL.

Quinocip Eye Ointment: Sterile ophthalmic ointment containing ciprofloxacin 0.3% w/w, equivalent to 3 mg ciprofloxacin per gram. **Presentation:** 3.5 g.

Ciprofloxacin is a synthetic fluoroquinolone antibacterial agent for topical ophthalmic use. Exact salt form and inactive ingredients are according to the approved finished-product formula.

CLINICAL PHARMACOLOGY

Ciprofloxacin is bactericidal. It inhibits bacterial DNA gyrase and topoisomerase IV, enzymes essential for bacterial DNA replication, transcription, repair and recombination. It has activity against a range of susceptible Gram-positive and Gram-negative organisms involved in ocular infections. Susceptibility varies by organism and region.

INDICATIONS

Eye Drops: Treatment of bacterial conjunctivitis and corneal ulcers caused by susceptible organisms, including selected strains of Staphylococcus, Streptococcus, Haemophilus influenzae and Pseudomonas aeruginosa (corneal ulcers).

Eye Ointment: Treatment of bacterial conjunctivitis caused by susceptible organisms. Use for other ocular infections only on the advice of an ophthalmologist and in accordance with locally approved indications.

Use only when bacterial infection is established or strongly suspected. Not effective against viral or fungal eye infections.

DOSAGE AND ADMINISTRATION

EYE DROPS - Bacterial conjunctivitis: Instill 1-2 drops into the affected eye(s) every 2 hours while awake for the first 2 days, followed by 1-2 drops every 4 hours while awake for the next 5 days, or as directed by the physician.

EYE DROPS - Corneal ulcer: Day 1: 2 drops every 15 minutes for the first 6 hours, then 2 drops every 30 minutes for the rest of the day. Day 2: 2 drops every hour. Days 3-14: 2 drops every 4 hours. Further treatment may be necessary on specialist assessment.

EYE OINTMENT - Bacterial conjunctivitis: Apply approximately a 1.25 cm (half-inch) ribbon into the conjunctival sac 3 times daily on days 1-2, then twice daily for the next 5 days, or as directed.

Wash hands before administration. Do not allow the dropper or tube tip to contact the eye, fingers or any surface. Close container securely. If more than one eye medicine is prescribed, separate drops by at least 5 minutes and apply ointment last.

CONTRAINDICATIONS

Known hypersensitivity to ciprofloxacin, other quinolone antibacterial agents, or any ingredient in the relevant formulation.

WARNINGS

FOR OPHTHALMIC USE ONLY. Not for injection into the eye. Discontinue immediately if rash, swelling, breathing difficulty or other signs of hypersensitivity occur; seek urgent medical care for a severe reaction.

Prolonged use may result in overgrowth of non-susceptible organisms, including fungi. Re-evaluate the patient if the condition worsens or does not improve. Corneal ulcers require close ophthalmic supervision.

PRECAUTIONS

Avoid touching the applicator tip to prevent contamination. Do not wear contact lenses during treatment of an active eye infection. Refrain from driving or using machinery if vision is blurred after application; ointment may cause transient blurring.

White crystalline corneal deposits can occur in some patients treated frequently with ciprofloxacin drops for corneal ulcers. Such deposits may resolve during therapy and do not always require cessation; ophthalmic review is essential.

DRUG INTERACTIONS

Specific topical ophthalmic interaction studies are limited. Systemic absorption is generally low, but tell the prescriber about all current medicines. Administer other ophthalmic products at suitable intervals; ointments should be used last.

PREGNANCY

Adequate controlled studies of topical ophthalmic ciprofloxacin in pregnancy are limited. Use only if the expected benefit justifies possible risk, following a physician's assessment.

LACTATION

Ciprofloxacin is excreted in human milk after systemic use. It is unknown whether topical ophthalmic dosing leads to clinically relevant amounts in milk. Use caution during breastfeeding and consult a healthcare professional.

PEDIATRIC AND GERIATRIC USE

Pediatric use and age limits should follow the approved labeling for each formulation. Published reference products have established use in selected pediatric populations. No general dosage adjustment is normally required solely on the basis of older age.

ADVERSE REACTIONS

Eye Drops: Transient burning, stinging or discomfort, foreign-body sensation, itching, conjunctival redness, eyelid crusting, unpleasant taste, tearing, photophobia and occasionally white corneal precipitates with intensive ulcer treatment.

Eye Ointment: Temporary eye discomfort, blurred vision, keratopathy, irritation, redness, tearing, itching, eyelid swelling and ocular pain may occur.

Both forms: Allergic reactions are possible. Stop treatment and obtain advice if severe irritation, rash, swelling or visual deterioration occurs.

OVERDOSAGE

Accidental excessive topical administration may be rinsed from the eye with lukewarm water. In case of accidental ingestion, seek medical advice; treatment is supportive.

STORAGE CONDITIONS

Store according to the approved product label. Protect from contamination; keep tightly closed. Do not freeze. Use within the approved in-use period after opening, where specified. Keep all medicines out of the reach of children.

PRESENTATION

Quinocip Eye Drops 0.3%: 5 mL sterile ophthalmic solution in dropper bottle.

Quinocip Eye Ointment 0.3%: 3.5 g sterile ophthalmic ointment in ophthalmic tube.

MANUFACTURED BY

Vega Pharmaceuticals (Pvt.) Ltd.