



KirOftal CiprOxyn®

REGISTRATION NUMBER Q-0790-132

BROAD-SPECTRUM BACTERICIDAL ANTIBIOTIC

FORMULATION:

Each mL contains:

Ciprofloxacin hydrochloride 3 mg

Chondroitin sulfate 200 mg

Vehicle q.s. 1 mL

DOSAGE SIZE AND FORM: 5 mL dropper bottle

VETERINARY USE

OPHTHALMIC SOLUTION

BROAD-SPECTRUM BACTERICIDAL ANTIBIOTIC

INDICATIONS:

KirOftal CiprOxyn® is indicated for the treatment of external infections of the eyeball such as bacterial conjunctivitis and corneal ulcers caused by susceptible Gram-positive and Gram-negative microorganisms. 20% Chondroitin sulfate accelerates regeneration and epithelial organization of the corneal stroma.

Ciprofloxacin is a second-generation fluoroquinolone. It acts against *Haemophilus influenzae*, *Pseudomonas aeruginosa*, *Serratia* spp, *Aeromonas* spp, *Campylobacter* spp, *Enterobacter* spp, *Haemophilus* spp, *Klebsella* spp, *Moraxella* spp, *Proteus* spp, *Salmonella* spp, *Shigella* spp, *Proteus* spp, *Neisseria* spp, *Shigella* spp, *Vibrio* spp, *Salmonella* spp. Gram-positive bacteria such as: *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Streptococcus* spp, *Enterococcus* spp. Other organisms such as *Chlamydia* spp. and *Mycobacterium* spp. Most strains of *Pseudomonas* spp; as well as most anaerobic bacteria, including *Bacteroides* spp and *Clostridium difficile*.

Ciprofloxacin acts by inhibiting DNA gyrase, an enzyme that controls the maturation process of the bacterial chromosome, causing the death of the bacteria. It also acts against the formation and replication of plasmids and bacteriophages. This fluoroquinolone is mainly useful for established corneal infections by gram-negative bacteria. Not recommended for prophylactic use before or after surgery.

There are no animal studies, only human studies on absorption in patients who started with one drop of ciprofloxacin ophthalmic suspension in each eye every two hours for two days, followed by a regimen of one drop in each eye every four hours for the next 5 days. Under this regimen, the fraction of ciprofloxacin that was absorbed after topical administration reported a maximum plasma concentration of ciprofloxacin of less than 5 ng/mL. The mean concentration was generally less than 2.5 ng/mL.

Chondroitin sulfate (CS) is a sulfated glycosaminoglycan (GAG) composed of a chain of alternating N-acetylgalactosamine and N-glucuronic acid disaccharides. CS is one of the main constituent elements of cartilage, which binds to a core protein, constituting the proteoglycan, which gives cartilage its mechanical and elastic properties.

Proteoglycans represent a special class of glycoproteins that are highly glycosylated. They consist of a protein center with one or more covalently linked glycosaminoglycan (GAG) chains. Proteoglycans can be divided according to the nature of their GAG chains.





These chains can be: CS, dermatan sulfate, heparin and heparan sulfate, and keratan sulfate, which possesses the characteristic of forming solutions of high viscosity and low opalescence, so it is used as a viscosifying agent in lubricant formulations; also, it inhibits proteolytic enzymes contained in tears. These enzymes increase during inflammation and are also produced by numerous bacteria, such as *Pseudomonas aeruginosa*.

Chondroitin sulfate favors cell growth and ulcer healing, promotes the production of fibronectin that generates repairing and healing effects, allowing cell growth and ulcer healing without leaving scars.

Chondroitin sulfate favors cell growth and ulcer healing, and also promotes the production of fibronectin that generates repairing and healing effects of the ulcer without leaving scars. They do not have intraocular penetrating capacity; however, they increase the precorneal tear film breakup time.

PRECAUTIONS / ADVERSE EFFECTS

Ciprofloxacin may cause crystalline crusts or precipitates in the superficial portion of the cornea. Other possible adverse effects with quinolones include: conjunctival hyperemia, bad taste, foreign body sensation with itching, photophobia, eyelid edema, keratitis, lacrimation and nausea. Allergic reactions have been reported with quinolone eye preparations.

SPECIES:

Canines, felines and equines (not intended for human consumption)

DOSE:

Apply one drop in each eye every 8, 12 or 24 hours for 2 days, then apply 1 drop every 12 - 24 hours for 5 days or at Veterinary Doctor's discretion.

ROUTE OF ADMINISTRATION:

Ophthalmic only.

DRUG-DRUG AND OTHER INTERACTIONS:

No drug-drug interactions have been found due to the low topical absorption of the components of the formulation.

WARNINGS AND/OR RESTRICTIONS:

"Do not administer in Equines intended for human consumption". The most frequent adverse reaction is immediate, acute and transient local burning. Pruritus, hyperemia, superficial punctate keratitis, foreign body reflex, lacrimation and photophobia may also occur. Whitish precipitates have been observed in cornea and palpebral margin that disappear spontaneously some days or weeks later and do not prevent completing the treatment. Keep in a dry, cool place, at a range of 15 - 30°C and protected against direct sunlight. Keep out of reach of children and pets. Product for exclusive use in Veterinary Medicine.

CONSULT A VETERINARY DOCTOR AVAILABLE BY PRESCRIPTION ONLY

Exclusive information for Doctors of Veterinary Medicine.

Made in Mexico by:

LABORATORIOS KIRON MEXICO S.A. de C.V.

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