USER INFORMATION

CIPOFAIN
Ciprofloxacin Sterile Ophthalmic Solution 0.3% w/v

Composition:
Each mL solution contains Ciprofloxacin Hydrochloride 3.5mg corresponding to 3mg of Ciprofloxacin and Benzalkonium Chloride 0.006%w/v as preservative.

Product Description:
Ciprofloxacin sterile ophthalmic solution is a sterile, aqueos solution of Ciprofloxacin Hydrochloride. The solution is a clear and colourless to pale yellow solution

Pharmacology:
Pharmacodynamics:
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 organisms both in vitro and in clinical infections.
Gram-Positive:
Staphylococcus aureus (including methicillin-susceptible and methicillin-resistant strains)
Staphylococcus epidermidis
Staphylococcus pneumonia
Streptococcus (Virridans Group)
Gram-Negative:
Haemophilus influenza
Pseudomonas aeruginosa
Serratia marcescens
Ciprofloxacin has been shown to be active in vitro against most strains of the following organisms; however, the clinical significance of these data is unknown:
Gram-Positive:
Enterococcus faecalis (many strains are only moderately susceptible)
Staphylococcus haemolyticus
Staphylococcus hominis
Staphylococcus saprophyticus
Steptococcus pyogenes
Gram-Negative:

Acinetobacter calcoaceticus subsp. anitratus	*Escherichia coli*	*Proteus vulgaris*
Aeromonas cavia	*Haemophilus ducreyi*	*Providencia rettgeri*
Aeromonas hydrophilia	*Haemophilus parainfluenza*	*Providencia stuartii*
Brucella melitensis	*Klebsiella pneumonia*	*Salmonella enteritidis*
Campylobacter coli	*Klebsiella oxytoca*	*Salmonella typhi*
Canpylobacter jejuni	*Legionella pneumophila*	*Shigella sonneii*
Citrobacter diversus	*Moraxella (Branhamella) catarrhalis*	*Shigella flexneri*
Citrobacter freundii	*Morganella morganii*	*Vibro cholerae*
Edwardsiella tarda	*Neisseria gononhoeae*	*Vibro parahaemolyticus*
Enterobacter aerogenes	*Neisseria meningitidis*	*Vibro vulnificus*
Enterobacter cloacae	*Pasteurella multocida*	*Yersinia enterocolitica*
	Proteus mirabilis	

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 mos anaerobic bacteria, including *Bacteroides fregilis* 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 wlth other antimicrobial agents such as beta-lactams or aminoglycosides; therefore, organisms resistant to these drugs may be susceptible to ciprofloxacin.

Pharmacokinetics:
After topical ocular administration, ciprofloxacin is also absorbed systemically. There are no pharmacokinetic data available in respect of use in children.

Indication:
Indicated for the treatment of infection caused by susceptible strains of the designated microorganisms in the condition listed below:
Corneal Ulcers: *Pseudomonas aeruginosa, Serratia mcarcescens, Staphylococcus aureus, Staphylococcus epidermidis, Streptococcus pneumonia, Streptococcus (Viridans Group)*
Conjunctivitis: *Haemophilus influenza, Staphylococcus aureus, Staphylococcus epidermidis, Streptococcus pneumonia.*

Recommended Dosage:
The recommended dosage regimen for the treatment of corneal ulcers is:
Day 1 : Instill 2 drops into the affected eye every 15 minutes for the first 6 hours and then 2 drops into the affected eye every 30 minutes for the remainder of the first day
Day 2 : Instill 2 drops in the affected eye hourly
Day 3 - 14 : Place 2 drops in the affected eye every 4 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.

Route of administration: FOR TOPICAL OPHTHALMIC USE ONLY

Contraindications:
Hypersensitivity to the active substance or to any of the recipients and hypersensitivity to quinolones.

Warnings and Precautions :
The use of CIPOFAIN eye drops in neonates with ophthalmia neonatorum of gonococcal or chalamydial origin is not recommended. Neonates with ophthalmia neonatorum should receive appropriate treatment for their condition.
When using CIPOFAIN eye drops one should take into account the risk of rhinopharyngeal passage which can contribute to the occurrence and the diffusion of bacterial resistance. Serious and occasionally fatal hypersensitivity (anaphylactic) reactions, some following the first dose, were observed in patients receiving treatment based on systematically administered quinolones. Some reactions were accompanied by cardiovascular collapse, loss of consciousness, tingling, pharyngeal or facial oedema, dyspnea, urticaria and itching. Only a few patients had a history of hypersensitivity reactions.
As with all antibacterial preparations prolonged use may lead to overgrowth of non-susceptible bacterial strains or fungi. If superinfection occurs, appropriate therapy should be initiated.
Ciprofloxacin should be discontinued at the first appearance of skin rash or any other sign of hypersensitivity.
During therapy, soft contact lenses should not be worn.
Exacerbation of myasthenia gravis
Fluoroquinolones have neuromuscular blocking activity and may exacerbate muscle weakness in person with myasthenia gravis. Post marketing serious adverse events, including deaths and requirement for ventilator support have been associated with flouroquinolones use in persons with myasthenia gravis. Avoid flouroquinolones in patients with known history of myasthenia gravis

Caution:
For topical ophthalmic use only. Not for injection into the eye.
Discard 28 days after first opening. Do not use if leakage is detected. Do not touch ampoule tip to any surface, as this may contaminate the solution.

Interactions with Other Medicaments:
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, to interfere with the metabolism of caffeine, and to enhance the effect of the oral anticoagulant, warfarin, and its derivatives. Transient elevation in serum creatinine has been reported in patients receiving cyclosporin concomitantly with systemic ciprofloxacin.

Incompatibility:
Incompatible with alkaline solutions.

Adverse Effects/Undesirable Effects:
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. Other reactions occurring in fewer patients included lid margin crusting, crystals /scales, foreign body sensation, itching, conjunctival hyperemia and a bad taste following instillation. Additional events occurring included corneal staining, keratopathy/keratitis, allergic reactions, lid edema, tearing, photophobia, corneal infiltrates, nausea and decreased vision.
Exacerbation of myasthenia gravis
Post Marketing Experience

Statement on Usage During Pregnancy and Lactation:
As there are no controlled studies in pregnant women CIPOFAIN should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus.
Orally administered ciprofloxacin is excreted in the human milk. Excretion of ciprofloxacin into human milk following topical ophthalmic administration has not been investigated. Therefore, caution should be exercised when CIPOFAIN is administered to nursing mothers.

Overdose and Treatment:
A topical overdose of CIPOFAIN may be flushed from the eye(s) with warm tap water.

Storage Condition Before and After Opening:
Do not store above 30°C. Protect from light.

Shelf life:
2 years from manufacturing date in the proposed storage condition. Discard 28 days after first opening. Do not use after expiry.

Dosage form and packaging available:
5mL X 1 bottle per box

Manufacturer/Product Registration Holder:
AIN MEDICARE SDN. BHD.
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Date of Revision: 01.10.2019