NORFLOX Eye Drops/Ear Drops/Eye Ointment (Norfloxacin 0.3%)

**Composition**

Each ml contains:
- Norfloxacin USP................... 0.3% w/v
- Benzalkonium chloride NF (preservative)...0.01% w/v
- Sterile aqueous vehicle.........................q.s.

**Dosage Form**

- Eye/Ear Drops
- Eye Ointment

**Description**

NORFLOX eye/ ear drops and NORFLOX eye ointment are sterile preparations of norfloxacin, a broad-spectrum fluoroquinolone antibacterial. It exerts its bactericidal effect by inhibiting the DNA gyrase, an essential enzyme involved in DNA replication.

**Pharmacology**

**Pharmacodynamics**

NORFLOX eye/ ear drops and NORFLOX eye ointment are sterile preparations of norfloxacin, a broad-spectrum fluoroquinolone antibacterial. It exerts its bactericidal effect by inhibiting the DNA gyrase, an essential enzyme involved in DNA replication.

Norfloxacin has *in vitro* activity against a broad spectrum of gram-positive and gram-negative aerobic bacteria. The fluorine atom at the 6 position provides increased potency against gram-negative organisms and the piperazine moiety at the 7 position is responsible for anti-pseudomonal activity.

Norfloxacin inhibits bacterial deoxyribonucleic acid synthesis and is bactericidal.

At the molecular level three specific events are attributed to norfloxacin in *E. coli* cells:
1. Inhibition of the ATP-dependent DNA super coiling reaction catalyzed by DNA gyrase,
2. Inhibition of the relaxation of super coiled DNA,
3. Promotion of double-stranded DNA breakage.

There is generally no cross-resistance between norfloxacin and other classes of antibacterial agents. Therefore, norfloxacin generally demonstrates activity against indicated organisms resistant to some other antimicrobial agents. When such cross-resistance does occur, it is probably due to decreased entry of the drugs into the bacterial cells. Antagonism has been demonstrated *in vitro* between norfloxacin and nitrofurantoin.

Norfloxacin has been shown to be active against most strains of the following organisms both *in vitro* and
clinically in ophthalmic infections.
Gram-positive Bacteria
Staphylococcus aureus
Staphylococcus epidermidis
Staphylococcus warnerii
Streptococcus pneumoniae
Gram-negative Bacteria
Acinetobacter calcoaceticus
Aeromonas hydrophila
Haemophilus influenzae
Proteus mirabilis
Pseudomonas aeruginosa
Serratia marcescens
Norfloxacin has been shown to be active in vitro against most strains of the following organisms; however, the clinical significance of these data in ophthalmic infections is unknown.
Gram-positive Bacteria
Bacillus cereus
Enterococcus faecalis (formerly Streptococcus faecalis)
Staphylococcus saprophyticus
Gram-negative Bacteria
Citrobacter diversus
Citrobacter freundii
Edwardsiella tarda
Enterobacter aerogenes
Enterobacter cloacae
Escherichia coli
Hafnia alvei
Haemophilus aegyptius (Koch-Weeks bacillus)
Klebsiella oxytoca
Klebsiella pneumoniae
Klebsiellarhino scleromatis
Morganella morganii
Neisseria gonorrhoeae
Proteus vulgaris
Providenciaal califaciens
Providencia rettgeri
Providencia stuartii
Salmonella typhi
Vibrio cholerae
Vibrio parahemolyticus
Yersinia enterocolitica
Other
Ureaplasma urealyticum
Norfloxacin is not active against obligate anaerobes.
Pharmacokinetics

After topical instillation of 5 drops of Norfloxacin into human eyes, the concentration in cornea was 15.5 +/- 2.1 micrograms/g.

Indications

Eye

Norfloxacin ophthalmic solution is indicated for the treatment of conjunctivitis.

Ear

Otitis externa, acute otitis media and chronic suppurative otitis media and prophylaxis during otic surgeries such as mastoid surgery.

Dosage And Administration

Eye

The recommended dose in adults and paediatric patients (one year and older) is one or two drops of norfloxacin ophthalmic solution applied topically to the affected eye(s) four times daily for seven days. Depending on the severity of the infections, the dosage for the first day of therapy may be one or two drops every two hours during the waking hours.

Ear

Two or three drops every two or three hours, initially, reducing the frequency of instillation gradually as infection is controlled.

NORFLOX Eye Ointment

Apply a 1/2 ribbon into the conjunctival sac three times a day on the first two days, and then apply a 1/2 ribbon two times a day for the next five days.

Contraindications

Contraindicated in patients with history of hypersensitivity to norfloxacin or other members of quinolone group of antibacterial agents or any of the components of this medication.

Warnings And Precautions

General

NOT FOR INJECTION INTO THE EYE.

Serious and occasionally fatal hypersensitivity (anaphylactoid or 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 oedema, dyspnea, urticaria, and itching. Only a few patients had a history of hypersensitivity reactions. Serious anaphylactoid or anaphylactic reactions require immediate emergency treatment with epinephrine. Oxygen, intravenous steroids and airway management, including intubation, should be administered as indicated. As with other antibiotic preparations, prolonged use may result in overgrowth of non-susceptible organisms,
including fungi. If super infection occurs, appropriate measures should be initiated. Whenever clinical judgment dictates, the patient should be examined with the aid of magnification, such as slit lamp biomicroscopy and, where appropriate, fluorescein staining.

There have been reports of bacterial keratitis associated with the use of multiple dose containers of topical ophthalmic products. These containers have been inadvertently contaminated by patients who, in most cases, had a concurrent corneal disease or a disruption of the ocular epithelial surface.

**Drug Interactions**

Specific drug interaction studies have not been conducted with topical norfloxacin. However, the systemic administration of some quinolones has been shown to elevate plasma concentrations of theophylline, interfere with the metabolism of caffeine, and enhance the effects of the oral anticoagulant warfarin and its derivatives. Elevated serum levels of cyclosporine have been reported with concomitant use of cyclosporine with norfloxacin. Therefore, cyclosporine serum levels should be monitored and appropriate cyclosporine dosage adjustments made when these drugs are used concomitantly.

**Pregnancy**

**Teratogenic Effect**

*Pregnancy Category C*

NORFLOX eye/ear drops/ointment should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus.

**Lactation**

It is not known whether norfloxacin is excreted in human milk following ocular administration. Because many drugs are excreted in human milk, and because of the potential for serious adverse reactions in nursing infants from norfloxacin, a decision should be made to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

**Paediatric Use**

Safety and effectiveness in infants below the age of one year have not been established.

**Geriatric Use**

No overall differences in safety or effectiveness have been observed between elderly and young patients.

**Undesirable Effects**

In clinical trials, the most frequently reported drug-related adverse reaction was local burning or discomfort. Other drug-related adverse reactions were conjunctival hyperemia, chemosis, photophobia and a bitter taste following instillation.

**Overdosage**

An overdose of this medication is unlikely to occur. If an overdose is suspected, wash the eye with water and call an emergency room or poison control center. If the drops have been ingested, drink plenty of fluid and call an emergency center for advice.

**Incompatibility**

Not applicable.
Shelf-Life

3 years

Packaging Information

NORFLOX Eye/Ear Drops: ......................Vial of 10 ml
NORFLOX Eye Ointment: ......................Tube of 5 mg

Information For Patients

Patients should be instructed to avoid allowing the tip of the dispensing container to contact the eye or surrounding structures.

Patients should also be instructed that ocular preparations, if handled improperly or if the tip of the dispensing container contacts the eye or surrounding structures, can become contaminated by common bacteria known to cause ocular infections. Serious damage to the eye and subsequent loss of vision may result from using contaminated preparations. If redness, irritation, swelling, or pain persists or becomes aggravated, the patient should be advised to consult a physician.

Patients should also be advised that if they have ocular surgery or develop an intercurrent ocular condition (e.g., trauma or infection), they should immediately seek their physician's advice concerning the continued use of the present multidose container.

Patients should be advised that norfloxacin may be associated with hypersensitivity reactions, even following a single dose, and to discontinue the drug at the first sign of a skin rash or other allergic reaction. Patients should be advised not to wear contact lenses if they have signs and symptoms of bacterial conjunctivitis.

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