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

Qualitative And Quantitative Composition

NORFLOX Eye/Ear Drops
Each mL contains:
Norfloxacin USP................................................0.3% w/v
Benzalkonium Chloride NF (preservative).........0.01% w/v
Sterile aqueous vehicle.................................q.s.

NORFLOX Eye Ointment
Norfloxacin USP................................................0.3% w/w

Dosage Form(S) And Strength(S)

Norfloxacin 0.3% Eye/Ear Drops
Norfloxacin 0.3% Eye Ointment

Clinical Particulars

Therapeutic Indications
NORFLOX Eye/Ear Drops are indicated for the management of bacterial infection of the eyes and ears.
NORFLOX Eye Ointment is indicated for the management of bacterial infection of the eyes.

Posology and Method of Administration

NORFLOX Eye Drops
The recommended dose in adults and paediatric patients (1 year of age and older) is one or two drops of norfloxacin ophthalmic solution applied topically to the affected eye(s) four times daily for 7 days. Depending on the severity of the infections, the dosage for the first day of therapy may be one or two drops every 2 hours during the waking hours.

NORFLOX Ear Drops
Two or three drops every 2 or 3 hours, initially, reducing the frequency of instillation gradually as infection is controlled.

NORFLOX Eye Ointment
Apply a half-inch ribbon of ointment into the conjunctival sac three times a day on the first 2 days; then, for the next five days, apply a half-inch ribbon of ointment two times a day.

Contraindications

NORFLOX Eye/Ear Drops and NORFLOX Eye Ointment are 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.

Special Warnings and Precautions for Use
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.

General
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 judgement 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.

Drugs 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.

Use in Special Populations

Pregnant Women
Teratogenic Effect – Category C
NORFLOX Eye/Ear Drops and NORFLOX Eye Ointment should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus.

Lactating Women
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 Patients
Safety and effectiveness in infants below the age of 1 year have not been established.
Although quinolones, including norfloxacin, have been shown to cause arthropathy in immature animals after oral administration, topical ocular administration of other quinolones to immature animals has not shown any arthropathy and there is no evidence that the topical dosage form of those quinolones has any effects on the weight-bearing joints.

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

Effects on Ability to Drive and Use Machines
Not known.

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 hyperaemia, chemosis, photophobia, and a bitter taste following instillation. Systemic Absorption of fluoroquinolones has been reported to cause following adverse effects: The drug may cause low blood sugar and mental health related side effects. Low blood sugar levels, also called hypoglycemia, can lead to coma. The mental health side effects more prominent and more consistent across the systemic fluoroquinolone drug class are as mentioned below;

Disturbances in attention
Disorientation
Agitation
Nervousness
Memory impairment
Serious disturbances in mental abilities called delirium

If you experience any side effects, talk to your doctor or pharmacist or write to drugsafety@cipla.com. You can also report side effects directly via the National Pharmacovigilance Programme of India (PvPI) by calling on 1800 267 7779 (Cipla number) or you can report to PvPI on 1800 180 3024. By reporting side effects, you can help provide more information on the safety of this product.

Overdose
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 centre. If the drops have been ingested, drink plenty of fluids and call an emergency centre for advice.

Pharmacological Properties

Mechanism of Action
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.

Pharmacodynamic Properties

Microbiology
Norfloxacin has \textit{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 \textit{Escherichia coli} cells:

- Inhibition of the ATP-dependent DNA super-coiling reaction catalysed by DNA gyrase.
- Inhibition of the relaxation of super-coiled DNA.
- 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 \textit{in vitro} between norfloxacin and nitrofurantoin.

Norfloxacin has been shown to be active against most strains of the following organisms, both \textit{in vitro} and clinically, in ophthalmic infections.
Gram-positive Bacteria
Staphylococcus aureus
Staphylococcus epidermidis
Staphylococcus warneri
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
Klebsiellae rhino 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.
Pharmacokinetic Properties

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

Non-Clinical Properties

Animal Toxicology or Pharmacology

The oral administration of single doses of norfloxacin, six times the recommended human oral dose, caused lameness in immature dogs. Histologic examination of the weight-bearing joints of these dogs revealed permanent lesions of the cartilage. Related drugs also produced erosions of the cartilage in weight-bearing joints and other signs of arthropathy in immature animals of various species.

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.

Pharmaceutical Particulars

Incompatibilities

Not applicable

Shelf-Life

As on the pack

Packaging Information

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

Storage and Handling Instructions

Protect from light

Patient Counselling Information

What is NORFLOX Eye/Ear Drops and NORFLOX Eye Ointment?

Norfloxacin is an antibiotic and NORFLOX Eye/Ear Drops and Eye Ointment is used to treat bacterial infections of the eye and ears.

Do not take if you have an allergy to Norfloxacin

Do not use NORFLOX Eye/Ear Drops and NORFLOX Eye Ointment if you have allergy to norfloxacin or any other quinolone antibiotic or any other part of NORFLOX Eye/Ear Drops and Eye Ointment.

Before you take NORFLOX Eye/Ear Drops and NORFLOX Eye Ointment, tell your doctor about other medication.

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. If you are using more than one type of eye or ear medicine.
How should I take NORFLOX Eye/Ear Drops and NORFLOX Eye Ointment?
Always use NORFLOX Eye/Ear Drops and NORFLOX Eye Ointment exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

What are the possible side effects?
Like all medicines, NORFLOX Eye/Ear Drops and NORFLOX Eye Ointment can cause side effects, although not everybody gets them.
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.
The most frequently reported drug-related adverse reaction was local burning or discomfort. Other drug-related adverse reactions were conjunctival hyperaemia, chemosis, photophobia, and a bitter taste following instillation.

How should I store NORFLOX Eye/Ear Drops and NORFLOX Eye Ointment?
Store at room temperature. Do not freeze.
Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets.
Keep the bottle tightly closed.
Do not use the drops after the expiry date on the bottle and the carton. The expiry date refers to the last day of that month.

General information about the safe and effective use of Drug.
NORFLOX Eye/Ear Drops indicated for the management of bacterial infection of the eyes and ears. and NORFLOX Eye Ointment is indicated for the management of bacterial infection of the eyes.
Do not use norfloxacin Eye/Ear Drops and Eye Ointment if you have a viral or fungal infection in your eye. It is used to treat infections caused by bacteria only.
It is not known whether norfloxacin Eye/Ear Drops and Eye Ointment will harm an unborn baby. Do not use norfloxacin ophthalmic without first talking to your doctor if you are pregnant.
It is also not known whether norfloxacin Eye/Ear Drops and Eye Ointment passes into breast milk. Do not use norfloxacin ophthalmic without first talking to your doctor if you are breast-feeding a baby.
Do not to wear contact lenses if they have signs and symptoms of bacterial infection.

What are the ingredients of (Drug name) and contents of the pack?
Each ml of NORFLOX Eye/Ear Drops contains Norfloxacin 0.3% w/v and Benzalkonium Chloride NF 0.01% w/v (as a preservative).
NORFLOX Eye Ointment contain Norfloxacin 0.3% w/v.

Any other information.
Do not touch tip to any surface as this may contaminate the ointment.
Do not use the product if the imprinted carton seals have been damaged, or removed.

Details Of The Manufacturer

NORFLOX Eye/Ear Drops
CIPLA LTD
ADITI PHARMACEUTICALS PVT LTD (709103)
E 65/66, M.I.D.C.,
Akkalkot Road, Solapur-413006
District: SOLAPUR
NORFLOX Eye Ointment
CIPLA LTD.
Mumbai Central,
Mumbai - 400008

**Details Of Permission Or Licence Number With Date**

NORFLOX Eye/Ear Drops - 28A-PD/3280-A Date: 18/04/2018
NORFLOX Eye Ointment - NA

**Date Of Revision**

13/11/2019

**NORFLOX Eye Drops/Ear Drops/Eye Ointment**

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