Ofloxacin Inoflox® 3mg/mL Otic Drops

Topical Antibacterial

FORMULATION

Each mL solution contains:

Ofloxacin	3 mg (0.3%)
Sodium chloride	9 mg (0.9%)
Benzalkonium chloride solution (10%)	0.25 µL
(0.025 mg Benzalkonium chloride)	
Dilute Hydrochloric acid	q. s. to adjust pH to 5.5 to 6.7
Sodium hydroxide	q. s. to adjust pH to 6 to 7
Sterile Purified water	q. s. to 1 mL

PRODUCT DESCRIPTION

Ofloxacin (Inoflox) Otic Solution is a sterile, clear, pale yellow liquid.

PHARMACODYNAMICS

Ofloxacin is a synthetic broad-spectrum antimicrobial agent which inhibits DNA topoisomerase, more commonly referred to as the DNA gyrase. DNA gyrase is necessary for bacterial DNA replication and some aspects of transcription, repair, recombination, and transposition. Inhibition of DNA gyrase in susceptible microorganisms results in the inhibition of ATP-dependent negative supercoiling of DNA, inhibition of ATP-independent relaxation of supercoiled DNA, and promotion of double-stranded DNA breakage resulting in bacterial cell death.

ANTIMICROBIAL SPECTRUM OF ACTIVITY

Ofloxacin is active in vitro and clinically in otic infections against most strains of the following microorganisms:

Gram-positive Aerobic and Facultative Microorganisms	*Staphylococcus aureus*
	Streptococcus pneumoniae
Gram- negative Aerobic and Facultative Microorganisms	*Escherichia coli*
	Haemophilus influenzae
	Moraxella catarrhalis
	Proteus mirabilis
	Pseudomonas aeruginosa

PHARMACOKINETICS

The extent of otic and systemic absorption of Ofloxacin after topical application to the ear has not been fully elucidated. Serum concentrations achieved after topical application to the ear are minimal relative to those produced by oral or parenteral doses of the drug.

Topical application of Ofloxacin to the ear is associated with minimal penetration into the middle ear when the tympanic membrane is intact, however, Ofloxacin penetration is enhanced when the tympanic membrane is perforated.

Some systemic absorption of Ofloxacin occurs after topical application to the ear. After single administration of 10 drops of Ofloxacin 0.3% otic solution in adult patients with tympanostomy tubes with or without otorrhea, serum Ofloxacin concentrations averaged 4.1 or 5.4 ng/mL, respectively. Peak serum concentration at 10 ng/mL is achieved after topical application of Ofloxacin 0.3% otic solution in adults with perforated tympanic membranes .

Ofloxacin concentrations in middle ear mucosa showed considerable interindividual variation and ranged from undetectable to 602 mcg/g after administration of Ofloxacin 0.3% otic solution in adults with perforated tympanic membranes.

After administration of Ofloxacin 0.3% otic solution in patients with perforated tympanic membranes, Ofloxacin concentrations in otorrhea ranged from 389 to 2850 mcg/g 30 minutes after the dose.

INDICATIONS

For the treatment of external ear infections.

DOSAGE AND ADMINISTRATION

INDICATIONS	AGE GROUP	DOSE OF OFLOXACIN OTIC SOLUTION	DURATION OF TREATMENT
Otitis externa	Children 6 months to 13 years	5 drops instilled into the affected ear once daily	7 days
	Adults and children over 13 years	10 drops instilled into the affected ear once daily	7 days
Acute otitis media with tympanostomy tubes	Children 1 to 12 years	5 drops instilled into the affected ear twice daily	10 days
Chronic suppurative otitis media with perforated tympanic membranes	Adults and children 12 years or older	10 drops instilled into the affected ear twice daily	14 days

Or, as prescribed by a physician.

Directions for Use:

Turn the cap clockwise until the cap comes in contact with the shoulder of the container. This punctures the inner seal. The solution is now ready for use.



For Patients with Otitis Externa:

1. Incline the head sideways with the affected ear upwards
2. Instill the recommended dose of Ofloxacin Otic Drops into the affected ear
3. Keep the head inclined sideways for five minutes to facilitate penetration of the drops into the ear
4. Wipe off excess solution with clean cotton
5. Repeat for the opposite ear if needed

For patients with Acute Otitis Media and Chronic Suppurative Otitis Media:

1. Refer to steps 1 to 2 in the Directions for Use for Patients with Otitis Externa
2. Pump the tragus of the ear (a small cartilaginous flap in front of the external opening of the ear) four times by pushing inward to facilitate penetration of the drops into the middle ear
3. Refer to steps 3 to 5 in the Directions for Use for Patients with Otitis Externa

Information for Patients: Avoid contaminating the applicator tip with material from the finger or other sources to preserve the sterility of the drops.

CONTRAINDICATIONS

- Hypersensitivity to Ofloxacin or any other quinolone or any other component of the product

WARNINGS

Not for ophthalmic use.
Not for injection.

Serious and occasionally fatal hypersensitivity reactions, some after the initial dose, have been reported in patients receiving systemic Ofloxacin therapy. Some reactions were accompanied by cardiovascular collapse, loss of consciousness, angioedema (e.g., laryngeal, pharyngeal, or facial edema), airway obstruction, dyspnea, urticaria, and itching. If an allergic reaction to Ofloxacin is suspected, the patient should contact their doctor and discontinue Ofloxacin immediately. Serious acute hypersensitivity reactions may require emergency treatment. Oxygen and airway management, including intubation, should be administered as clinically indicated.

PRECAUTIONS

For external use only.

As with other anti-infectives, prolonged use of Ofloxacin may result in overgrowth of nonsusceptible organisms, including fungi. If superinfection occurs, discontinue Ofloxacin and institute appropriate therapy.

Cultures should be obtained if the infection is not improved after one week of treatment. If otorrhea persists after a full course of therapy, or if two or more episodes of otorrhea occur within six months, further evaluation is recommended to exclude underlying conditions such as cholesteatoma, foreign body or tumor.

Systemic administration of Ofloxacin at doses much higher than given or absorbed by the otic route has led to lesions or erosions of the cartilage in weight-bearing joints and other signs of arthropathy in immature animals of various species.

INTERACTIONS WITH OTHER MEDICATIONS

Specific drug interaction studies have not been performed to date with Ofloxacin otic. However, since systemic absorption may occur after topical application of Ofloxacin to the ear, the possibility of drug interactions such as those reported with systemic administration of some quinolone anti-infectives must be considered.

STATEMENT ON USAGE FOR HIGH RISK GROUPS

PREGNANCY AND LACTATION

Pregnancy: There have been no adequate and well-controlled studies using Ofloxacin Otic in pregnant women. Since Ofloxacin, like most other fluoroquinolones, can cause arthropathy in immature animals, Ofloxacin should not be used in pregnant women unless the benefits justify the potential risks.

Lactation: It is not known if Ofloxacin is excreted in human milk after otic administration. Therefore, do not administer to breastfeeding women unless, in the opinion of a physician, the potential benefits of the drug justify the possible risk.

PEDIATRIC USE

Safety and efficacy have been demonstrated in children of the following ages for the listed indications:

- Six months and older: Otitis externa with intact tympanic membranes
- One year and older: Acute otitis media with tympanostomy tubes
- Twelve years and older: Chronic suppurative otitis media with perforated tympanic membranes

Safety and efficacy in children below these ages have not been established.

UNDESIRABLE EFFECTS

The following adverse effects have been reported in patients with otitis externa: application site reaction, pruritus, earache, dizziness, headache, vertigo, nausea, seborrhea, loss of hearing, tinnitus, otitis externa, otitis media, tremor, hypertension, fungal infection, dermatitis, eczema, erythematous rash, follicular rash, hypoaesthesia, dyspepsia, hot flushes, flushing and otorrhagia (bleeding from the external auditory canal).

The following adverse effects have been reported in patients with acute otitis media with tympanostomy and chronic suppurative otitis media with perforated tympanic membranes: taste perversion, earache, pruritus, paresthesia, rash, and dizziness.

The following adverse effects have been reported in patients with perforated tympanic membranes: diarrhea, nausea, vomiting, dry mouth, headache, vertigo, otorrhagia, tinnitus, fever, application site reaction, otitis externa, urticaria, abdominal pain, dysaesthesia, hypersensitivities, halitosis, inflammation, pain, insomnia, cough, pharyngitis, rhinitis, sinusitis and tachycardia.

Cases of uncommon transient neuropsychiatric disturbances have been reported in postmarketing studies.

OVERDOSE AND TREATMENT

Currently, there is no information available on overdosage of Ofloxacin otic in humans.

ADVERSE DRUG REACTION REPORTING STATEMENT

For suspected adverse drug reaction, seek medical affirmation immediately and report to the FDA at www.fda.gov.ph AND Unilab at (+632) 858-1000 or productsafety@unilab.com.ph. By reporting undesirable effects, you can help provide more information on the safety of this medicine

STORAGE CONDITIONS

Always keep container tightly closed.
Keep the product out of reach and sight of children.
Store at temperatures not exceeding 30°C .

CAUTION

Foods, Drugs, Devices, and Cosmetics Act prohibits dispensing without prescription.

AVAILABILITY: Plastic bottle of 5 mL
Also available: 200 mg and 400 mg Tablets,
200 mg/100 mL Solution for Infusion and Ophthalmic Drops

Manufactured by
Santen Pharmaceutical Co., Ltd. Noto Plant
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