

SensofiTM

Eye / Ear Drops

(Ofloxacin Ophthalmic Solution IP 0.3% w/v)

COMPOSITION:

Ofloxacin IP	0.3% w/v
Benzalkonium Chloride Solution IP	0.02% v/v
(as preservative)	
Water for Injections IP	q.s.

List of Inactive Ingredients:

Sodium Chloride
Disodium edetate
Hydrochloric acid
Sodium Hydroxide

Pharmacological Action:

Ofloxacin acts against a broad range of gram-positive and gram-negative aerobic and anaerobic bacteria. Ofloxacin is bactericidal at concentrations equal to or slightly greater than inhibitory concentrations. Ofloxacin is thought to exert a bactericidal effect on susceptible bacterial cells by inhibiting DNA gyrase, an essential bacterial enzyme which is a critical catalyst in the duplication, transcription and repair of bacterial DNA.

Indications & Usage Section:

Ofloxacin 0.3% has been shown to be active against most strains of the following organisms both in Eye / Ears infections.

Aerobes, Gram-Positive Microorganisms:

Staphylococcus aureus, Staphylococcus epidermidis and Streptococcus pneumoniae

Aerobes, Gram-Negative Microorganisms:

Enterobacteriaceae, Haemophilus influenza, Proteus mirabilis, Pseudomonas aeruginosa Serratia marcescens

Anaerobic Species Microorganisms: Propionibacterium acnes

Aerobes, Gram-Positive Microorganisms:

Enterococcus faecalis, Listeria monocytogenes, Staphylococcus capitis, Staphylococcus hominus, Staphylococcus simulans, Streptococcus pyogenes
Aerobes, Gram-Negative Microorganisms: Acinetobacter calcoaceticus var. anitratus, Acinetobacter calcoaceticus var. Iwoffl, Citrobacter diversus, Citrobacter freundii, Enterobacter aerogenes, Enterobacter agglomerans, Escherichia coli, Haemophilus parainfluenzae, Klebsiella oxytoca, Klebsiella pneumoniae, Moraxella catarrhalis, Moraxella lacunata, Morganella morganii, Neisseria gonorrhoeae, Pseudomonas acidovorans, Pseudomonas fluorescens, Shigella sonnei

Other Microorganisms: Chlamydia trachomatis

Contraindications: Ofloxacin 0.3% is contraindicated in patients with a history of hypersensitivity to ofloxacin 0.3%, to other quinolones, or to any of the components in this medication.

Warnings:

Sensofi (Ofloxacin 0.3%) should not be injected sub conjunctivally, nor should it be introduced directly into the anterior chamber of the eye. Serious and occasionally fatal hypersensitivity (anaphylactic) reactions, some following the first dose, have been reported in patients receiving systemic quinolones, including Ofloxacin 0.3%. Some reactions were accompanied by cardiovascular collapse, loss of consciousness, angioedema (including laryngeal, pharyngeal or facial edema), airway obstruction, dyspnea, urticaria, and itching. A rare occurrence of Stevens - Johnson syndrome, which progressed to toxic epidermal necrolysis, has been reported in a patient who was receiving topical ophthalmic Ofloxacin 0.3%. If an allergic reaction to Ofloxacin 0.3% occurs, discontinue the drug. Serious acute hypersensitivity reactions may require immediate emergency treatment. Oxygen and airway management, including intubation should be administered as clinically indicated.

Precautions:

General: As with other anti-infectives, prolonged use may result in overgrowth of non-susceptible organisms, including fungi. If super infection occurs discontinue use and institute alternative therapy. Whenever clinical judgment dictates, the patient should be examined with the aid of magnification, such as slit lamp biomicroscopy and, where

appropriate, fluorescein staining. Ofloxacin 0.3% should be discontinued at the first appearance of a skin rash or any other sign of hypersensitivity reaction.

Drug Interactions: Specific drug interaction studies have not been conducted with Ofloxacin 0.3%. However, the systemic administration of some quinolones has been shown to elevate plasma concentrations, interfere with the metabolism of caffeine, and enhance the effects of the oral anticoagulant warfarin and its derivatives, and has been associated with transient elevations in serum creatinine in patients receiving cyclosporine concomitantly.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Long term studies to determine the carcinogenic potential of Ofloxacin 0.3% have not been conducted.

Pregnancy: Sensofi (Ofloxacin 0.3%) can be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers: It is not known whether Ofloxacin 0.3% is excreted in human milk following topical ophthalmic administration. Because of the potential for serious adverse reactions from Ofloxacin 0.3% in nursing infants, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric 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 younger patients.

Adverse Reactions: The most frequently reported drug-related adverse reaction was transient ocular burning or discomfort. Other reported reactions include stinging, redness, itching, chemical conjunctivitis / keratitis, ocular / periocular / facial edema, foreign body sensation, photophobia, blurred vision, tearing, dryness, and eye pain. Rare reports of dizziness and nausea have been received.

Dosage and Administration:

The recommended dosage regimen for the treatment of bacterial conjunctivitis is:

Days 1 and 2

Instill one to two drops every two to four hours in the affected eye(s). Days 3 through 7

Instill one to two drops four times daily.

The recommended dosage regimen for the treatment of bacterial corneal ulcer is:

Days 1 and 2

Instill one to two drops into the affected eye every 30 minutes, while awake. Awaken at approximately four and six hours after retiring and instill one to two drops.

Days 3 through 7 to 9

Instill one to two drops hourly, while awake.

Days 7 to 9 through

Instill one to two drops, treatment completion four times daily.

Overdosage:

An overdose of this medication is unlikely to occur. If you do suspect an overdose, wash the eye with water and call an emergency room or poison control center near you.

Storage Instructions:

Use the solution within one month after opening the container.

Do not touch tip of container to any surface. Replace cap after using.

KEEP OUT OF REACH OF CHILDREN.

FOR EXTERNAL USE ONLY

NOT FOR INJECTION

KEEP IN A COOL PLACE

PROTECT FROM LIGHT

Presentation:

Sensofi (Ofloxacin 0.3%) is a sterile solution supplied in a opaque plastic dropper bottle with a cap, containing 5 ml of the solution.

Directions for use:



Turn the tamper proof cap anti-clockwise to break the seal.



Remove the cap, dispense drops with gentle pressure.

Replace the cap immediately after every use.

Manufactured in INDIA by :

Senses Pharmaceuticals Pvt. Ltd.,

No.77, 3rd Road, Bommasandra Industrial Area,
Bommasandra 4th Phase, Bengaluru - 560 099.

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