For the use of a Registered Medical Practitioner or a Hospital or a Laboratory

Ofloxacin Ophthalmic Solution USP 0.3% w/v

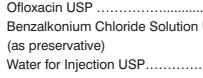
SENSOFI™

For the use of Registered Medical Practitioner only

Composition

Ofloxacin USP …….....……. 0.3% w/v
Benzalkonium Chloride Solution USP…..... 0.02% v/v
(as preservative)
Water for Injection USP……..……. q.s

Chemical Structure & Name



C18H20FN3O4

7*H* -Pyrido[1,2,3-*de*]-1,4-benzoxazine-6-carboxylic acid, 9-fluoro-2,3-dihydro-3-methyl-10- (4-methyl-1-piperazinyl)-7-oxo-,(±)-. (±)-9-Fluoro-2,3-dihydro-3-methyl-10-(4-methyl-l-piperazinyl)-7-oxo-7*H* -pyrido[1,2,3-de]-1,4-benzoxazine-6-carboxylic acid

Category

Pharmacotherapeutic group: Ophthalmological, anti-infective, fluoroquinolones

ATC code: S01AE01.

Description

Ophthalmic Solution.

A clear pale yellow color solution filled in 5mL Sterile Gamma-irradiated white opaque LDPE bottle sealed with Sterile Gamma-irradiated natural transparent LDPE open nozzle and Sterile Gamma-irradiated white HDPE tamp safe cap.

Pharmacology

Ofloxacin is a synthetic fluorinated 4-quinolone antibacterial agent with activity against a broad spectrum of Gram negative and to lesser degree Gram positive organisms. Ofloxacin has been shown to be active against most strains of the following organisms both *in vitro* and clinically in ophthalmic infections. Clinical trial evidence of the efficacy of Ofloxacin Ophthalmic Solution USP 0.3% w/v against S. *pneumoniae was* based on a limited number of isolates.

Gram-negative bacteria: *Acinetobactercalcoaceticusvar.* anitratum, and A. *calcoaceticus* var. iwoffi; Enterobacter Sp. including *E*. cloacae; Hemophilic Sp, including *H. influenza* and *H. aegyptius*; Klebsiella Sp., including K. *Pneumoniae;* Moraxella Sp., *Morganellamorganii;* Proteus Sp., including P. *Mirabilis;* Pseudomonas Sp.; including P. *Aeruginosa, P. cepacia,* and *P. fluoroscens;* and Serratia Sp., including S. *marcescens.*

Gram-positive bacteria: Bacillus Sp.; Corynebacterium Sp.; Micrococcus Sp.; Staphylococcus Sp., including S. *aureusand S. epidermidis;* Streptococcus Sp., including *S. Pneumoniae, S. viridansand* Beta-haemolytic.

The primary mechanisms of action are through inhibition of bacterial DNA gyres, the enzyme responsible for maintaining the structure of DNA.

Ofloxacin is not subject to degradation by beta-lactamase enzymes nor is it modified by enzymes such as aminoglycoside adenylases or phosphorylases, or chloramphenicol acetyltransferase.

Pharmacokinetic:

After ophthalmic instillation, ofloxacin is well maintained in the tear-film. In a healthy volunteer study, mean tear film concentrations of ofloxacin measured

four hours after topical dosing (9.2 μg/g) were higher than the 2μg/mL minimum concentration of ofloxacin necessary to inhibit 90% of most ocular bacterial strains (MIC90) *in-vitro*. Maximum serum ofloxacin concentrations after ten days of topical dosing were about 1000 times lower than those reported after standard oral doses of ofloxacin, and no systemic side effects attributable to topical ofloxacin were observed.

Indications

Ofloxacin Ophthalmic Solution USP0.3% w/v is indicated for the topical treatment of external ocular infections (such as conjunctivitis and keratoconjunctivitis) in adults and children caused by ofloxacin - sensitive organisms.

Safety and efficacy in the treatment of ophthalmianeonatorum has not been established.

Dosage & Administration

Method of Administration:

Topical ocular instillation.

For all ages: one to two drops in the affected eye(s) every two to four hours for the first two days and then four times daily. The length of treatment should not exceed ten days.

Contraindications

Ofloxacin Ophthalmic Solution USP is contra-indicated in individuals who have shown hypersensitivity to ofloxacin, any of its excipients or any other quinolones.

Warning and Precaution

Ofloxacin Ophthalmic Solution USP 0.3% w/v is not for injection.

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

Serious and occasionally fatal hypersensitivity (anaphylactic/anaphylactoid) reactions, some following the first dose, have been reported in patients receiving systemic quinolones, includingofloxacin. Some reactions were accompanied by cardiovascular collapse, loss of consciousness, angioedema (including laryngeal, pharyngeal or facial oedema), airway obstruction, dyspnoea, urticaria, and itching.

If an allergic reaction Ofloxacin Ophthalmic Solution USP 0.3% w/v occurs, discontinue the drug. Use Ofloxacin Ophthalmic Solution USP0.3% w/v with caution in patients who have exhibited sensitivities to other quinolones antibacterial agents.

When using Ofloxacin Ophthalmic Solution USP 0.3% w/v the risk of rhino-pharyngeal passage which can contribute to the occurrence and the diffusion of bacterial resistance should be considered. As with other anti-infective, prolonged use may result in overgrowth of non-susceptible organisms.

If worsening infection occurs, or if clinical improvement is not noted within a reasonable period, discontinue use and institute alternative therapy.

Cardiac disorders

Caution should be taken when using fluoroquinolones, including Ofloxacin Ophthalmic Solution USP 0.3% w/v in patients with known risk factors for prolongation of the QT interval such as, for example:

- Congenital long QT syndrome
- Concomitant use of drugs that are known to prolong the QT interval (e.g. Class IA and III anti-arrhythmic, tricyclic antidepressants, macrolides, antipsychotics)
- Uncorrected electrolyte imbalance (e.g. hypokalaemia, hypomagnesaemia)
- Cardiac disease (e.g. heart failure, myocardial infarction, bradycardia)

Elderly patients and women may be more sensitive to QTc-prolonging medications.

Therefore, caution should be taken when using fluoroquinolones, including Ofloxacin Ophthalmic Solution USP0.3% w/v, in these populations.

Use Ofloxacin Ophthalmic Solution USP 0.3% w/v with caution in patients who have exhibited sensitivities to other quinolone antibacterial agents.

Data are very limited to establish efficacy and safety of Ofloxacin Ophthalmic Solution USP 0.3% w/v in the treatment of conjunctivitis in neonates.
The use of Ofloxacin Ophthalmic Solution USP eye drops in neonates with ophthalmia neonatorum caused by Neisseria gonorrhoeae or Chlamydia trachomatis is not recommended as it has not been evaluated in such patients.
Use in elderly: No comparative data are available with topical dosing in elderly versus other age groups.
Clinical and non-clinical publications have reported the occurrence of corneal perforation in patients with pre-existing corneal epithelial defect or corneal ulcer, when treated with topical fluoroquinolone antibiotics. However, significant confounding factors were involved in many of these reports, including advanced age, presence of large ulcers, concomitant ocular conditions (e.g. severe dry eye), systemic inflammatory diseases (e.g. rheumatoid arthritis), and concomitant use of ocular steroids or non-steroidal anti-inflammatory drugs.
Nevertheless, it is necessary to advise caution regarding the risk of corneal perforation when using product to treat patients with corneal epithelial defects or corneal ulcers.
Corneal precipitates have been reported during treatment with topical ophthalmic ofloxacin. However, a causal relationship has not been established.
Long-term, high-dose use of other fluoroquinolones in experimental animals has caused lenticular opacities. However, this effect has not been reported in human patients, nor has it been noted following topical ophthalmic treatment with ofloxacin for up to six months in animal studies including studies in monkeys.
Ofloxacin Ophthalmic Solution USP 0.3% w/v contains the preservative benzalkonium chloride which may cause ocular irritation and discolor soft contact lenses.
Sun or UV-exposition should be avoided during use of ofloxacin due to the potential for photosensitivity.
Use of contact lenses is not recommended in patients receiving treatment for an eye infection.
No studies on the effects on the ability to drive and use machines have been performed.
Transient blurring of vision may occur on instillation of eye drops. Do not drive or operate hazardous machinery unless vision is clear.

Interactions

No interaction studies have been performed.
It has been shown that the systemic administration of some quinolones inhibits the metabolic clearance of caffeine and theophylline. Drug interaction studies conducted with systemic ofloxacin have demonstrated that metabolic clearance of caffeine and theophylline are not significantly affected by ofloxacin.
Although there have been reports of an increased prevalence of CNS toxicity with systemic dosing of fluoroquinolones when used concomitantly with systemic nonsteroidalantiinflammatory drugs (NSAIDs), this has not been reported with the concomitant systemic use of NSAIDs and ofloxacin.
Ofloxacin Ophthalmic Solution USP0.3% w/v like other fluoroquinolones, should be used with caution in patients receiving drugs known to prolong the QT interval (e.g. Class IA and III anti-arrhythmic, tricycle antidepressants, macrolides, antipsychotic

Pregnancy & Lactation

Use in pregnancy: There have been no adequate and well-controlled studies performed in pregnant women. Since systemic quinolones have been shown to cause arthropathy in immature animals, it is recommended that Ofloxacin Ophthalmic Solution USP 0.3% w/v not be used in pregnant women.
Use during lactation: Because ofloxacin and other quinolones taken systemically are excreted in breast milk, and there is potential for harm to nursing infants, a decision should be made whether to temporarily discontinue nursing or not to administer the drug, taking into account the importance of the drug to the mother.

Adverse reaction

General

Serious reactions after use of systemic ofloxacin are rare and most symptoms are reversible. Since a small amount of ofloxacin is systemically absorbed after topical administration, sideeffects reported with systemic use could possibly occur.

Frequency categories: Very common (≥ 1/10); Common (≥ 1/100 to < 1/10); Uncommon (≥ 1/1,000 to < 1/100); Rare (≥ 1/10,000 to < 1/1,000); Very rare (< 1/10,000) and not known (cannot be estimated from the available data):

Immune System Disorders

Not Known: Hypersensitivity reaction including signs or symptoms of Eye allergy (such as Eye pruritus and Eyelid pruritus) and Anaphylactic reactions (such as angioedema, dyspnea, anaphylactic shock, or pharyngeal swelling, facial oedema and tongue swollen)

Nervous System Disorders

Not known: Dizziness

Eye Disorders

Common: Eye irritation; Ocular discomfort

Not known: Keratitis; Conjunctivitis; Vision blurred; Photophobia; Eye oedema; Foreign body sensation in eyes; Lacrimation increased; Dry eye; Eye pain; Ocular hyperemia; Periorbitaloedema (including eyelid oedema)

Cardiac disorders

Not known: ventricular arrhythmia and torsades de pointes (reported predominantly in patients with risk factors for QT prolongation); ECG QT prolonged

Gastrointestinal Disorders

Not known: Nausea

Skin and Subcutaneous Tissue Disorders

Not Known: Stevens-Johnson syndrome; Toxic epidermal necrolysis Reporting of suspected adverse reactions

Overdosage

In the event of overdose, symptomatic treatment should be implemented. ECG monitoring should be undertaken, because of the possibility of QT interval prolongation.

Storage

Store between 15°C - 30 °C. Protect from light

Keep out of reach of children.

Shelf life

24 Months from the date of manufacture.

Presentation

A clear pale yellow color solution filled in 5mL Sterile Gamma-irradiated white opaque LDPE bottle sealed with Sterile Gamma-irradiated natural transparent LDPE open nozzle and Sterile Gamma-irradiated white HDPE tamp safe cap in printed carton along with leaflet.

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.
Email: info@sensespharma.com

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