120.00 mm

170.00 mm

Typhoxcin 0.3% w/v Ophthalmic Solution

(O f l o x a c i n)

ٹائیفوکسن ۰.۳%
جراثیم سے پاک
(اوفلوکساسن) آنکھوں کے قطرے

COMPOSITION
Each ml contains:
Ofloxacin ……3mg
(USP Specifications)

DESCRIPTION
Typhoxcin (Ofloxacin ophthalmic solution) 0.3% is a sterile ophthalmic solution. It is a fluorinated carboxyquinolone anti-infective for topical ophthalmic use.

INDICATIONS
Ofloxacin ophthalmic solution 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 ophthalmia neonatorum has not been established.

MECHANISM OF ACTION
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. The primary mechanisms of action are through inhibition of bacterial DNA gyrase, 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.

DOSAGE & 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.

PHARMACOKINETICS
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 2 µg/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.

WARNINGS & PRECAUTIONS
Ofloxacin ophthalmic solution 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, including ofloxacin. Some reactions were accompanied by cardiovascular collapse, loss of consciousness, angioedema (including laryngeal, pharyngeal or facial oedema), airway obstruction, dyspnea, urticaria, and itching. If an allergic reaction to Ofloxacin ophthalmic solution occurs, discontinue the drug. Use Ofloxacin ophthalmic solution with caution in patients who have exhibited sensitivities to other quinolones antibacterial agents.When using Ofloxacin ophthalmic solution 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-infectives, prolonged use may result in overgrowth of non-susceptibleorganisms.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 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 arrhythmics, 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, in these populations.
Use Ofloxacin ophthalmic solution 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 eye drops 0.3% in the treatment of conjunctivitis in neonates.
The use of Ofloxacin ophthalmic solution eye drops in neonates with ophthalmia neonatorum caused by Neisseria gonorrhoeae or Chlamydia trachomatis is not recommended as it has notbeen 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 contains the preservative benzalkonium chloride which may cause eye irritation, symptoms of dry eyes, and may affect the tear film and corneal surface.
Should be used with caution in dry eye patients and in patients where the cornea may be compromised.
Use of contact lenses is not recommended in patients receiving treatment for an eye infection. Patients should remove contact lenses prior to application and wait at least 15 minutes before reinsertion. Benzalkonium chloride is known to discolor soft contact lenses.
Patients should be monitored in case of prolonged use.
Sun or UV-exposition should be avoided during use of ofloxacin due to the potential for photosensitivity.
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 not be used in pregnant women.
Breastfeeding
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.

SIDE EFFECTS
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, side-effects reported with systemic use could possibly occur.
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, oropharyngeal 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; Periorbital oedema (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.

DRUG 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 nonsteroidal anti-inflammatory drugs (NSAIDs), this has not been reported with the concomitant systemic use of NSAIDs and ofloxacin.
Ofloxacin ophthalmic solution, like other fluroquinolones, should be used with caution in patients receiving drugs known to prolong the QT interval (e.g. Class IA and III antiarrhythmics, tricyclic antidepressants, macrolides, antipsychotics).

CONTRAINDICATIONS
Ofloxacin ophthalmic solution is contra-indicated in individuals who have shown hypersensitivity to ofloxacin, any of its excipients or any other quinolones.

OVER DOSAGE
No case of overdose has been reported.
In the event of a topical overdosage, flush the eye with water.
In the event of overdose, symptomatic treatment should be implemented. ECG monitoring should be undertaken, because of the possibility of QT interval prolongation.

STORAGE & INSTRUCTIONS
Store below 30°C.
Protect from heat, sunlight, moisture and do not freeze.
Keep away from the reach of the children.
Use within one month after first opening the bottle and discard the remaining portion.
Do not touch the dropper tip to any surface as this may contaminate the solution.
To be sold on the prescription of a registered medical practitioner only.
For ophthalmic use only.

HOW SUPPLIED
5ml sterile ophthalmic solution in a plastic dropper bottle.

خوراک وطریقہ استعمال:
ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
ہدایات:
دوا کو ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت میں رکھیں۔
دھوپ، گرمی اور نمی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔
صرف رجسٹرڈ ڈاکٹر کے نسخے کے مطابق فروخت کریں۔

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