

Ocuflox

Lomefloxacin 0.3%

Sterile and Pyrogen free Eye Drops

Composition

Each ml contains Lomefloxacin Hydrochloride INN equivalent to Lomefloxacin 3 mg. Preservative: Benzalkonium Chloride BP 0.02 mg.

Description

It is a sterile and pyrogen free ophthalmic solution containing Lomefloxacin-a difluorinated quinolone derivative for topical administration into the eyes.

Clinical Pharmacology

Lomefloxacin is a difluorinated quinolone. It is bactericidal with a broad spectrum of antibacterial activity. It interferes with bacterial DNA related processes like initiation, elongation and termination phases of replication, transcription, DNA repair, recombination, transposition, supercoiling and relaxation of DNA. The target molecule for quinolones is the A subunit of bacterial enzyme gyrase (topoisomerase II). The forming of a stable complex between the quinolone and the whole gyrase tetramer A2B2 leads to impaired enzyme functions, resulting in a rapid killing of sensitive bacteria. Plasmid mediated transfer of resistance has not been observed so far. Cross-resistance has only been reported with other quinolones, but not with any other group of antibiotics.

Pharmacokinetics

In animal studies, tear levels after two applications of 50 µl 0.3% Lomefloxacin were at 40-200 µg/ml at 2 hours and still 7-27 µg/ml at 6 hours. Even at 24 hours more than 3 µg/ml were observed. Although these results can not directly be transferred to the human eye since physiology of the cornea and penetration through the cornea vary considerably between rabbits and humans, penetration of Lomefloxacin through the human cornea has been confirmed. In humans, concentrations of 1.3-2.7 µg/ml in the anterior chamber have been found 90-180 min after topical application. This concentration, however, may not be high enough for the treatment of endophthalmitis. Systemic absorption following topical ophthalmic application of 0.3% Lomefloxacin eye drops is very low. After application of four times daily 2 drops during two weeks, blood levels were below the detection limit of 0.005 µg/ml.

Indications

Lomefloxacin is indicated for bacterial infections, including bacterial conjunctivitis, blepharitis and blepharo-conjunctivitis which are due to Lomefloxacin susceptible germs. It is also indicated for the treatment of keratitis and corneal ulcer.

Dosage & Administration

Adults and children (above 1 year of age): Instill one drop 2 times daily into the lower conjunctival sac. At the beginning of treatment, application should be more frequent, apply 5 drops within 20 minutes or 1 drop every hour during 6 -10 hours.

Contraindications

It is contraindicated in persons with a known hypersensitivity to any component of this product

Precautions

It contains benzalkonium chloride as a preservative, which can permeate into soft hydrophilic contact lenses. For this reason soft hydrophilic contact lenses should be taken out before applying Ocuflox eye drops and be replaced after 15 minutes.

Side-Effects

Slight and transient burning immediately after instillation of the eye drops has been reported in 4.7% of users. Although phototoxicity has not been reported after ophthalmic use, photosensitization is possible. Since the following allergic reactions have been reported after systemic use of Lomefloxacin, they cannot be excluded after topical ophthalmic use: allergic reactions, asthma, dyspnoea, urticaria, erythema, pruritus and hypersensitization.

Pregnancy & Lactation

Animal studies have revealed that after systemic use, Lomefloxacin passes the placental barrier and is also excreted in maternal milk. Clinical studies on the use of Lomefloxacin eye drops during human pregnancy or lactation are not available. The drug therefore, should only be used when the potential benefit to the pregnant/lactating woman outweighs the potential risk to the fetus or the infant.

Overdosage

There is no risk of adverse effects due to accidental oral ingestion since a bottle of 5 ml eye drops contains only 15 mg Lomefloxacin. This corresponds to < 4% of the recommended oral daily dose for adults.

Drug Interactions

In order to avoid reduction of efficacy, no ophthalmic preparations containing heavy metals, such as zinc, should be used during 15 minutes preceding and following application of the eye drops.

Pharmaceutical Precautions

Store at room temperature and protect from light. It is desirable that the contents should not be used more than one month after first opening of the bottle.

Commercial Pack

Plastic dropper bottle of 5 ml.