Mexlo® Eye Drops

Lomefloxacin 0.3%
Sterile solution

Lomefloxacin, a difluorinated quinolone derivative, is a bacterial gyrase inhibitor, effective against gram positive and gram negative bacteria. The acute toxicity of Lomefloxacin following systemic and topical ophthalmic application is low. Lomefloxacin interferes with bacterial DNA related processes like initiation, elongation, and termination phases of replication, transcription, DNA repairing, recombination, transposition, supercoiling and relaxation of DNA. The target molecule for quinolones is the A-subunit of bacterial enzyme gyrase (topoisomerase II).

Sensitive germs
Gram-positive: *Staphylococcus epidermidis, S. aureus, Bacillus, Corynebacterium.*
Gram-negative: *Branhamella catarrhalis, Neisseria spp., Acinetobacter spp., Alcaligenes faecalis, Enterobacter spp., Flavobacterium spp., Haemophilus influenzae, Klebsiella, Moraxella, Proteus, Pseudomonas aeruginosa, Pseudomonas spp., Serratia spp.*
Anaerobic germs: *Propionibacterium acnes.*

COMPOSITION
Mexlo® 0.3% Eye Drops : Each ml contains Lomefloxacin 3 mg (as Lomefloxacin hydrochloride INN 3.31 mg).

INDICATION
Bacterial infections, including conjunctivitis, blepharitis, blepharoconjunctivitis which are due to Lomefloxacin susceptible germs and *Staphylococcus aureus* - induced corneal ulcers.

DOSAGE AND ADMINISTRATION
Adults and children (*above 1 year of age*): Insert 1 drop 2-3 times daily into the lower conjunctival sac. At the beginning of the treatment, applications should be more frequent, apply 5 drops within 20 minutes or 1 drop every hour during 6-10 hours.
Duration of the treatment: 7 to 9 days.

CONTRAINDICATION
Hypersensitivity to the active ingredient, to excipients, or to quinolones.

PRECAUTION
Long term treatment with antibiotics may enhance development of secondary fungal infections or may support growth of non susceptible bacteria. Some isolated cases of phototoxicity have been reported after systemic but not after topical ophthalmic use of Lomefloxacin. Nevertheless, during treatment with Lomefloxacin intensive exposure to sunlight or UV-radiation should be avoided.

SIDE EFFECT
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 can not be excluded after topical ophthalmic use: allergic reactions, asthma, dyspnoea, urticaria, erythema, pruritus, and hypersensitization.

DRUG INTERACTION
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 Lomefloxacin.
Bacteriostatic ophthalmic antibiotics should not be used concomitantly with Lomefloxacin eye drops.

USE IN PREGNANCY AND LACTATION
Clinical studies on the use of Lomefloxacin eye drops during human pregnancy or lactation are not available. Therefore, the drug should only be used when the benefit outweighs the potential risk for the foetus or the infant.

OVERDOSE
Practically there is no risk of adverse effects due to accidental oral ingestion, since a bottle of 5 ml eye drop solution contains only 15 mg Lomefloxacin. This corresponds to 3.75% of the recommended oral daily dose for adults of 400 mg Lomefloxacin.

STORAGE
Store below 30^0C in a cool and dry place protected from light. Keep out of reach of children. Do not touch the dropper tip to surfaces since this may contaminate the solution. Do not use after 30 days of first opening.

HOW SUPPLIED
Mexlo® 0.3% Eye Drops: Each plastic dropper bottle contains 5 ml of Lomifloxacin 0.3% sterile solution.

Manufactured by
SQUARE
PHARMACEUTICALS LTD.
BANGLADESH