

## **Contra® Eye Drops**

(Lomefloxacin INN 0.3%)

**Description:** Lomefloxacin, a difluorinated quinolone derivative, is a bacterial gyrase inhibitor, effective against gram positive and gram negative bacteria. Lomefloxacin interferes with bacterial DNA related processes like initiation, elongation and termination phases of replication, transcription, DNA repair, recombination, transposition, super-coiling and relaxation of DNA, resulting in a rapid killing of sensitive bacteria. Cross-resistance has only been reported with other quinolones, but not with any other group of antibiotics. No clinical studies are available about the efficacy in case infections with chlamydia.

**Indications:** Lomefloxacin is indicated for bacterial infections, including conjunctivitis, blepharitis and blepharo-conjunctivitis which are due to Lomefloxacin susceptible germs.

**Dosage and Administration:** Adults and children (above 1 year of age): Apply 2-3 times daily 1 drop into the lower conjunctival sac. At the beginning of the treatment application 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.

**Contraindications:** Hypersensitivity to the active ingredient, to excipients, or to quinolones. No adverse effects were noted in children included in clinical studies, although this data are limited. Adverse 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.

**Precautions:** Long term treatment with antibiotic 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.

**Pregnancy & Lactation:** After high systemic doses of Lomefloxacin (50-100mg/kg), variations of caudal vertebrae have been observed in rabbit foetus. Furthermore, animal studies revealed that after systemic use of 20 mg/kg, Lomefloxacin passes the placenta barrier and is excreted into the maternal milk. 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. Drug Interactions: In order to avoid reduction of efficacy, no ophthalmic preparation 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. Other interactions have not been described to date.

**Overdosage:** There is practically no risk of adverse effect due to accidental oral ingestion, since a bottle of 5 ml eye drop solution contains only 15 mg Lomefloxacin. This corresponds to 3.7% of the recommended oral daily dose for adults of 400 mg Lomefloxacin. In case of systemic ingestion irrigation of the stomach may be appropriate in young children to decrease further absorption.

**Pharmaceutical Precautions:** Store in a cool and dry place, away from light. Keep out of reach of children.

**Commercial Pack:** Contra® 0.3% Eye Drops: Plastic dropper bottle contains 5 ml sterile eye drops. Each ml contains Lomefloxacin Hydrochloride INN equivalent to Lomefloxacin INN 3 mg.

Manufactured by

BEXIMCO PHARMACEUTICALS LTD.

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