

Exocin™ Abbreviated Prescribing Information

Presentation: A clear, odourless aqueous ophthalmic solution of ofloxacin 0.3% (w/v).

Indications: EXOCIN 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. **Dosage and administration:** 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.

Pharmacology: Ofloxacin is a synthetic fluorinated 4-quinolone antibacterial agent.

Contraindications: EXOCIN is contraindicated in patients sensitive to ofloxacin or any of its other components.



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Use during 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 EXOCIN be used in pregnant women only if the potential benefit justifies the potential risk to the foetus. **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.

Precautions: As with other anti-infectives, 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. Use EXOCIN with caution in patients who have exhibited sensitivities to other quinolone antibacterial agents. EXOCIN should not be used while patients are wearing hydrophilic (soft) contact lenses. **Adverse reactions:** Transient ocular irritation has been reported. Since ofloxacin is systemically absorbed after topical administration, side effects reported with systemic use could possibly occur. **Overdosage:** In the event of a topical overdosage, flush eye with water.

Legal category: POM. **Package quantities:** EXOCIN is supplied in plastic dropper bottles containing 5 ml solution. Basic NHS Price £2.65. **Further information:** The primary mechanism of action is through inhibition of bacterial DNA gyrase, the enzyme responsible for maintaining the structure of DNA. **Product licence number:** 0426/0070. **References:** 1. Osato M.S. et al. Am J Ophthalmol 1989; 108:380-386. 2. Crump G.C. et al. M J Drugs 34 (Suppl 1): 1-8 (1987). 3. Brown A.J. et al. Br J Ophthalmol (1991) 75:675-679.

The treatment of ocular infections is about to enter a new era with the launch of EXOCIN.

A new ocular quinolone antibiotic with a dual mode of action, EXOCIN offers extra reassurance when treating in the absence of bacteriological identification. With potent bactericidal activity(1) against most gram +ve and gram -ve organisms, including Staphylococci and Pseudomonas, you can be confident that EXOCIN drops will deal with infections quickly and effectively.

And because EXOCIN's action on bacterial DNA gyrase has been shown to deter the development of resistance (2), there's no need to consider it as a 'reserve'. Indeed, with the increasing resistance to chloramphenicol(3) EXOCIN should be considered as your first choice in the treatment of eye infections.

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 **ALLERGAN**

Allergan Limited
High Wycombe
Bucks HP12 3ST
United Kingdom

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