




EMLc

ATC codes: S01AE01

|                         |   |
|-------------------------|---|
| Indication              | Infectious keratitis <span style="background-color: #008080; color: white; padding: 2px;">ICD11 code: 9A71</span>   |
| INN                     | Ofloxacin   |
| Medicine type           | Chemical agent  |
| Antibiotic groups       | <span style="border: 1px solid #008080; padding: 2px;">WATCH</span>   |
| List type               | Core  |
| Formulations            | Local > Ophthalmological > Solution (eye drops): 0.3%   |
| EML status history      | First added in 2013 (TRS 985)   |
| Sex                     | All   |
| Age                     | Also recommended for children   |
| Therapeutic equivalence | Medicines within the same pharmacological class can be used   |
| Patent information      | Patents have expired in most jurisdictions<br>Read more <a href="#">about patents</a> .  |
| Wikipedia               | <a href="#">Ofloxacin</a>    |
| DrugBank                | <a href="#">Ofloxacin</a>    |

### Summary of evidence and Expert Committee recommendations

An application was submitted by the International Council of Ophthalmology for the addition of ofloxacin 0.3% for infectious keratitis in Section 21.1 which included only gentamicin 0.3%. It has been estimated that up to 5% of all blinding conditions in developing countries are directly related to ocular trauma and the subsequent infection (1). This estimate is supported by population-based studies in several countries. In a blindness survey in Nepal, corneal trauma and ulceration were found to be the second leading cause of unilateral visual loss after cataract, accounting for 7.9% of all blind eyes. A study in south India found that the incidence of ulcerative keratitis was 11.3 cases per 10 000 persons, resulting in an estimate of 840 000 new ulcers annually in India alone. The application provided data on one clinical trial in which ofloxacin 0.3% was compared with fortified gentamicin (1.5%) plus cefuroxime (5%) in microbial keratitis, and which showed similar rates of cure. The authors stated that treatment with ofloxacin monotherapy was associated with less toxicity but did not provide data (2). Another trial was identified in the expert reviews in which ofloxacin was found to be more effective than gentamicin (3). Ofloxacin eye drops have been approved for the treatment of bacterial keratitis by Australia, the United Kingdom and the US FDA. In summary, ofloxacin eye drops have been shown to be as effective as other antibiotic eye drops and potentially to have less toxicity. The clinical trials cited in the application did not show ofloxacin to be clearly superior to any of the commonly used antibiotic eye drops. It has the advantage of being affordable and widely available. However, the other fluoroquinolones may be widely available and equally affordable in different settings. The Expert Committee recommended that ofloxacin ophthalmic solution should be added to the EML and the EMLc with a square box symbol. References: 1. Whitcher JP, Srinivasan M. Corneal ulceration in the developing world—a silent epidemic. *Br J Ophthalmol*. 1997;81(8):622-3. <http://dx.doi.org/10.1136/bjo.81.8.622> PMID:9349145 2. The Ofloxacin Study Group. Ofloxacin monotherapy for the primary treatment of microbial keratitis: a double-masked, randomized, controlled trial with conventional dual therapy. *Ophthalmology*. 1997;104(11):1902-9. [http://dx.doi.org/10.1016/S0161-6420\(97\)30009-8](http://dx.doi.org/10.1016/S0161-6420(97)30009-8) PMID:9373124 3. Gwon A; Ofloxacin Study Group. Topical ofloxacin compared with gentamicin in the treatment of external ocular infection. *Br J Ophthalmol*.

