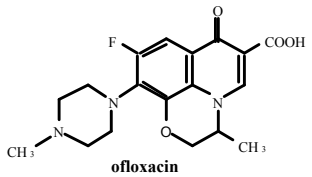
BPCA Summary of NDA 19-921 (b) (4)
Pediatric Supplement

NDA 19-921 (b) (4) **Submission Date:** December 19, 2002

Trademark: Ocuflox

Generic Name: ofloxacin ophthalmic solution 0.3%

Chemical Name:



ofloxacin

Mol Wt 361.37
ofloxacin $C_{17}H_{18}FN_3O_3 \bullet HCl \bullet H_2O$

(±)-9-Fluoro-2,3-dihydro-3-methyl-10-(4-methyl-1-piperazinyl)-7-oxo-7H-pyrido[1,2,3-de]-1,4 benzoxazine-6-carboxylic acid

Sponsor:

Allergan, Inc.
2525 Dupont Drive
P.O. Box 19534
Irvine, California 92623-9534

Contact: Elizabeth Bancroft
800-347-4500

Pharmacologic Category: Anti-infective (fluoroquinolone)

Related INDs: IND (b)(4)---
IND (b)(4)--

Related NDAs: NDA 19-921

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Executive Summary

1 Recommendations

(b) (4)

1.2 Recommendation on Phase 4 Studies

No Phase 4 studies are recommended.

2 Summary of Clinical Findings

2.1 Brief Overview of Clinical Program

Ofloxacin is a fluoroquinolone anti-infective agent. Topical ofloxacin ophthalmic solution 0.3% is approved in the United States for the treatment of infections caused by susceptible microorganisms in conjunctivitis and corneal ulcers in patients above the age of one year.

There are currently no approved products to treat neonatal bacterial conjunctivitis (i.e. bacterial conjunctivitis in infants between birth to one month of age).

The sponsor conducted a 7-day multi-center, randomized, double-masked, parallel-group clinical trial that compared topical ofloxacin 0.3% ophthalmic solution (Ocuflox) to topical trimethoprim sulfate/polymyxin b sulfate combination ophthalmic solution (Polytrim) in neonates from birth to 31 days of age in response to an October 22, 1999 written request (amended on August 3, 2001 and September 6, 2002) from the agency for pediatric information on the safety and efficacy of ofloxacin ophthalmic solution (NDA 19-921).

(b) (4)

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2.3 Safety

The safety data contained in this submission is comparable to that reported for previously approved Ocuflox ophthalmic solution 0.3%, NDA 19-921.

2.4 Dosing

No change to the current dosing regimen is proposed in this submission.

2.5 Special Populations

No additional data on special populations was obtained

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/s/

Wiley Chambers

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