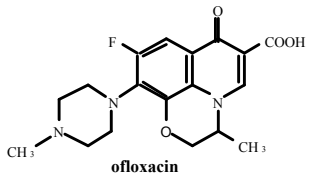
BPCA Summary of NDA 19-921/SE5-018
Pediatric Supplement

NDA 19-921/SE5-018 **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

1.1 Recommendation on Approvability

Supplemental NDA 19-921/SE5-018 is not recommended for approval for the treatment of bacterial conjunctivitis in neonates from birth to 1 month of age.

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).

2.2 Efficacy

The submitted study in supplemental NDA 19-921/SE5-018 is not sufficient to establish efficacy for the use of Ocuflox ophthalmic solution 0.3% in the treatment of bacterial conjunctivitis in neonates from birth to 1 month of age.

The clinical cure rate of Ocuflox (60%) is approximately 10% less than the 70% cure rate generally associated with vehicle treatment. The microbiological eradication rate for susceptible microorganisms at Day 7 for each treatment group is 55% for Ocuflox and 50% for Polytrim.

Although the clinical cure rate for Ocuflox in this trial is greater than that demonstrated for Polytrim (48%), the study results are not adequate to demonstrate the efficacy of Ocuflox in the treatment of neonatal conjunctivitis.

It is not possible to determine from the data submitted whether the low clinical cure rate seen in this study is due to factors related to the design of the study, the dosing frequency of the ofloxacin ophthalmic solution 0.3%, the particular organisms associated with these cases of bacterial conjunctivitis, the conduct of the study, or a combination of these factors.

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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