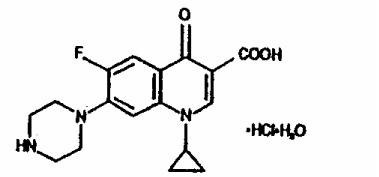
BPCA Summary of NDA 19-992/SE5-017
Pediatric Supplement

NDA 19-992/SE5-017 **Submission Date:** October 14, 2002

Trademark: Ciloxan

Generic Name: Ciprofloxacin hydrochloride ophthalmic Solution, 0.3%

Chemical Name:



Mol Wt 385.8
ciprofloxacin $C_{17}H_{18}FN_3O_3 \bullet HCl \bullet H_2O$
1-cyclopropyl-6-fluoro-1, 4-dihydro-4-oxo-7-(1-piperazinyl)-3-quinoline-carboxylic acid

Sponsor:

Alcon, Inc.
P.O. Box 62
Bosch 69
CH-6331 Hunenberg
Switzerland

Authorized U.S. Agent
Alcon Research, Ltd.
6201 S. Freeway
Fort Worth, Texas
(817) 551-4933
Contact: Angela Kothe

Pharmacologic Category: Anti-infective (fluoroquinolone)

Related INDs: IND 30,537 Ciprofloxacin solution
IND 31,864 Ciprofloxacin ointment

Related NDAs: NDA 19-992 Ciloxan Solution
NDA 20-369 Ciloxan Ointment

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Executive Summary

1 Recommendations

1.1 Recommendation on Approvability

Supplemental NDA 19-992/SE5-017 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 and/or Risk Management Steps

No Phase 4 studies and/or risk management steps are recommended.

2 Summary of Clinical Findings

2.1 Brief Overview of Clinical Program

Ciprofloxacin is a fluoroquinolone antibacterial agent. Ophthalmic ciprofloxacin is approved in the United States for the treatment of infections caused by susceptible microorganisms in corneal ulcers and conjunctivitis. Ciprofloxacin hydrochloride (Ciloxan) ophthalmic solution 0.3% is indicated for the treatment of corneal ulcers and conjunctivitis in patients ages 1 year older, whereas Ciloxan ophthalmic ointment 0.3% is indicated for the treatment of conjunctivitis only in patients ages 2 years and older.

In response to an October 22, 1999 written request (which was amended on August 3, 2001 and September 6, 2002) from the agency for pediatric information on the safety and efficacy of ciprofloxacin ophthalmic solution (NDA 19-992), sponsor conducted a 9-days multicenter, randomized, double-masked, parallel group study that compared Ciloxan 0.3% TID to moxifloxacin ophthalmic solution 0.5% TID in neonates from birth to 1 month of age. There are currently no approved products to treat neonatal bacterial conjunctivitis.

2.2 Efficacy

The submitted study in supplemental NDA 19-992/SE5-017 is not sufficient to establish efficacy for the use of Ciloxan ophthalmic solution 0.3% in the treatment of bacterial conjunctivitis in neonates from birth to 1 month of age. Ciloxan's clinical cure rate (61%) is approximately 10% less than the cure rate generally associated with vehicle treatment (approximately 70%). Although the clinical cure rate for Ciloxan is numerically greater than MOXFX (53%) and reaches 80% for each of the treatment group by the test-of-cure visit (day 9), the study results are not adequate to demonstrate efficacy of Ciloxan.

2.3 Safety

The safety data contained in this submission is comparable to that reported for previously approved Ciloxan ophthalmic solution 0.3%, NDA 19-992.

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 are needed.