Effect of Once-Daily Bromfenac Ophthalmic Solution on Photophobia Associated with Cataract Surgery

DE Beahm, MD, 1 RL Berry, MD, 2 L Cacioppo, MD, 2 R Bianca, PhD, 3 JA Gow, MD, 4 TR McNamara, PharmD 5 for the Bromfenac Ophthalmic Solution Once Daily Study Group

1Beahm Eye Center, Great Bend, KS; 2Eye Care Arizona, PA; Little Rock, AR; 3Hernando Eye Institute, Brooksville, FL; 5ISTA Pharmaceuticals, Inc., Irvine, CA

ABSTRACT

To evaluate the effect of bromfenac ophthalmic solution administered once daily on photophobia associated with cataract surgery.

Methods: Subjects were assigned randomly to receive either bromfenac ophthalmic solution QD (n=360) or placebo QD (n=182). Dosing began 1 day before cataract surgery and continued post-surgery. Photophobia was rated on a four point (0 to 3) scale. Rating was to be completed by the subject within 1 hour after instillation of test agent into the study (operative) eye and recorded in a diary.

Results: The proportion of subjects who were free of photophobia was significantly greater in the bromfenac treatment group than in the placebo treatment group by Day 1 (62% vs 53%; p<0.05), Day 3 (78% vs 65%; p<0.01), Day 8 (90% vs 73%; p<0.0001), and Day 15 (90% vs 73%; p<0.0001).

Conclusion: Bromfenac ophthalmic solution QD was effective for the treatment of photophobia associated with cataract surgery.

INTRODUCTION

• Bromfenac is a non-steroidal anti-inflammatory drug (NSAID) that works by blocking the production of prostaglandins, mediators of systemic and local (e.g., ocular) inflammation. 1
• Bromfenac (bromfenac sodium ophthalmic solution 0.1%) was approved in Japan in May 2000 for the treatment of patients with blepharitis, conjunctivitis, scleritis (including episcleritis) and post-operative inflammation.1,4-5
• Xibrom™ (bromfenac ophthalmic solution 0.09%), administered twice daily, was approved by the U.S. Food and Drug Administration (FDA) in March 2005 for the treatment of patients with post-operative ocular inflammation and in January 2006 for the treatment of patients with post-operative ocular pain.10
• Through December 2005, with more than 10 million uses of Bronuck in Japan and more than 204,000 uses of Xibrom in the U.S., there were no serious systemic drug-related adverse events reported, and no occurrence of spontaneously reported serious ocular adverse events was 0.0000025%.
• Based on extensive post-marketing experience and data from clinical trials, bromfenac ophthalmic solution has demonstrated an excellent safety profile.

Bromfenac ophthalmic solution QD is a new formulation of topical bromfenac to be administered once daily and is currently not approved by the FDA. This formulation should be more convenient for patients, should improve compliance with the treatment regimen, and should enhance clinical efficacy.

OBJECTIVE

• To evaluate the effect of bromfenac ophthalmic solution administered once daily on photophobia associated with cataract surgery.

RESULTS

The proportion of subjects who were free of photophobia was significantly greater in the bromfenac treatment group than in the placebo treatment group by Day 1 (62% vs 53%, p<0.05), Day 3 (78% vs 65%, p<0.01), Day 8 (90% vs 73%, p<0.0001), and Day 15 (90% vs 73%, p<0.0001).

Figure 1. Photophobia Score: Subjects (%) with Grade 0 by Visit

The mean photophobia score was significantly less in the bromfenac treatment group than in the placebo treatment group at Day 1 (0.5 vs 0.7, p<0.01), Day 3 (0.4 vs 0.8, p<0.0001), Day 8 (0.2 vs 0.8, p<0.0001), and Day 15 (0.2 vs 0.7, p<0.0001).

Figure 2. Photophobia: Mean Grade at Each Visit

REFERENCES


Financial support: ISTA Pharmaceuticals®, Inc., Irvine, CA, USA.

Financial disclosures: DEB, RLB, and LC were principal investigators. RBG, and JAR are affiliated with ISTA Pharmaceuticals®, Inc.