

Introducing an advanced formulation of BROMDAY® (bromfenac ophthalmic solution) 0.09%

PROLENSA™ POWERED FOR PENETRATION

PROLENSA™ delivers potency and penetration with QD efficacy^{1,2}

IMPORTANT RISK INFORMATION ABOUT PROLENSA™

Indications and Usage

PROLENSA™ (bromfenac ophthalmic solution) 0.07% is a nonsteroidal anti-inflammatory drug (NSAID) indicated for the treatment of postoperative inflammation and reduction of ocular pain in patients who have undergone cataract surgery.

Dosage and Administration

Instill one drop into the affected eye once daily beginning 1 day prior to surgery, continued on the day of surgery, and through the first 14 days post surgery.

Please see full Prescribing Information for PROLENSA™ inside pocket.

BAUSCH + LOMB

Warnings and Precautions

- Sulfite allergic reactions
- Slow or delayed healing
- Potential for cross-sensitivity
- Increased bleeding of ocular tissues
- Corneal effects, including keratitis
- Contact lens wear

Adverse Reactions

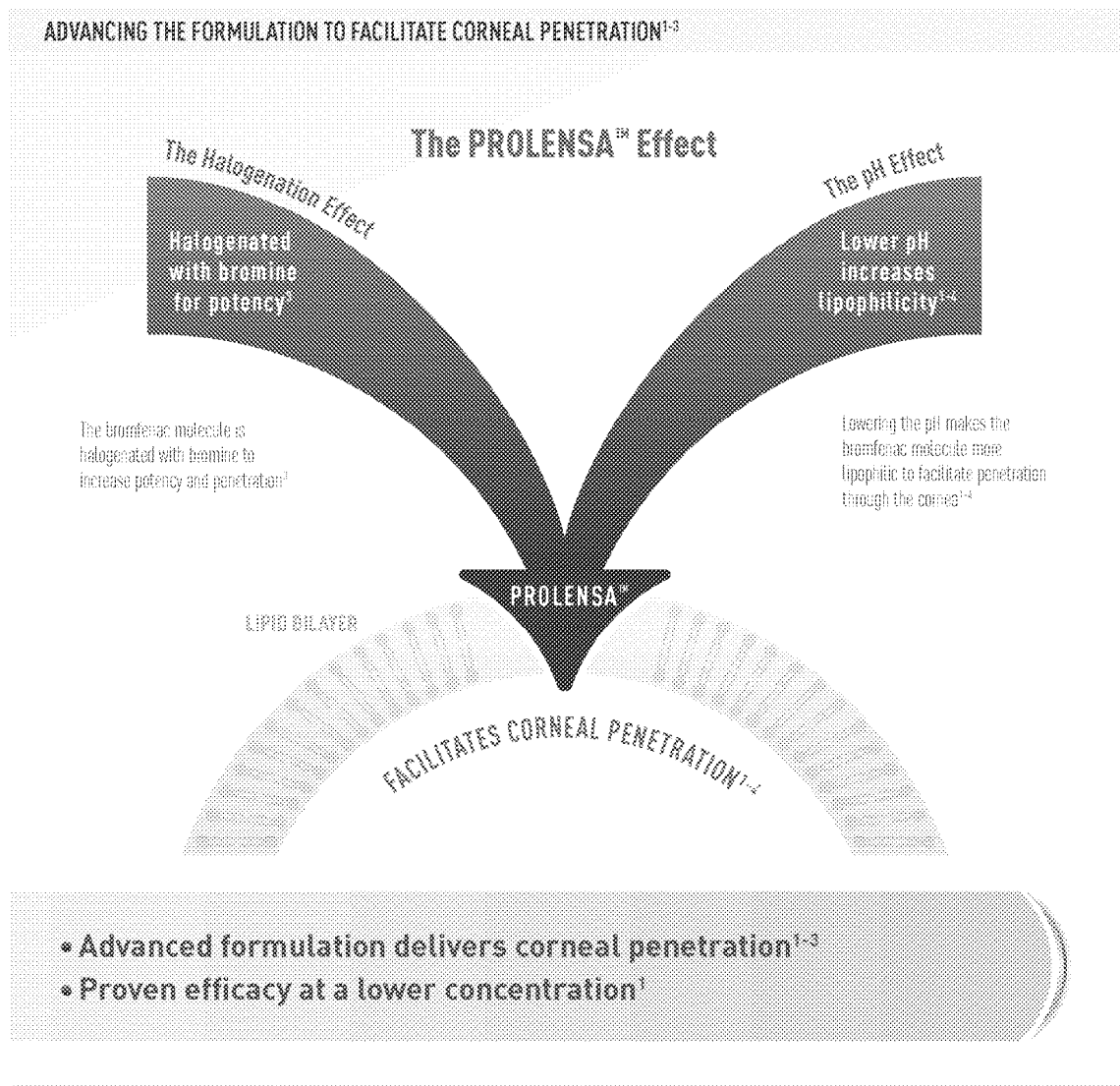
The most commonly reported adverse reactions in 3%-8% of patients were anterior chamber inflammation, foreign body sensation, eye pain, photophobia, and blurred vision.

PROLENSA™
(bromfenac ophthalmic
solution) 0.07%

CONFIDENTIAL

PROL0328434

PROLENSA™: Powered for penetration



IMPORTANT RISK INFORMATION ABOUT PROLENSA™

Indications and Usage

PROLENSA™ (bromfenac ophthalmic solution) 0.07% is a nonsteroidal anti-inflammatory drug (NSAID) indicated for the treatment of postoperative inflammation and reduction of ocular pain in patients who have undergone cataract surgery.

Warnings and Precautions

- Sulfite allergic reactions
- Slow or delayed healing
- Potential for cross-sensitivity
- Increased bleeding of ocular tissues
- Corneal effects, including keratitis
- Contact lens wear

Please see full Prescribing Information for PROLENSA™ inside pocket.

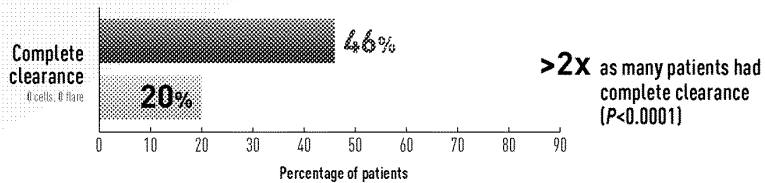
Study design: Clinical efficacy evaluated in 2 randomized, double-masked, vehicle-controlled trials of patients undergoing cataract surgery. Each randomized patient received PROLENSA™ or vehicle starting with one drop into surgical eye the day prior to and the day of surgery, and for 14 days post surgery. Study endpoints were clearing of ocular inflammation (SOBS-0) by Day 15 (primary) and the number of subjects pain free on Day 1 after surgery (secondary).¹

PROLENSA™: Powered for efficacy

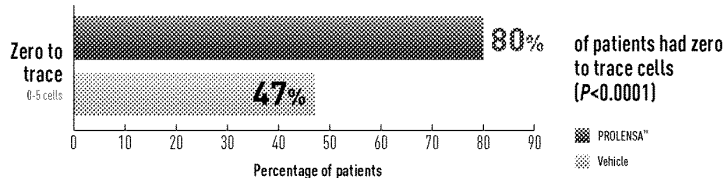
Powerful Clearance

INFLAMMATION CLEARANCE AT DAY 15^{1,2}

Primary endpoint: Complete clearance of cells and flare*



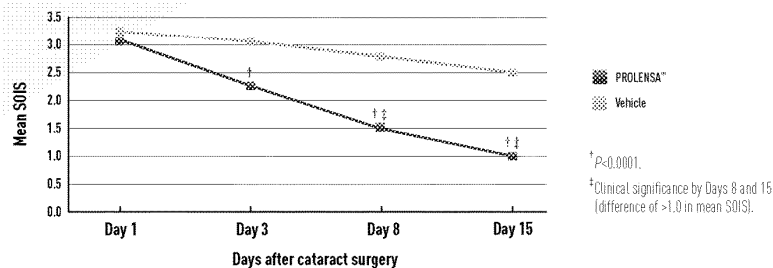
Additional prespecified endpoint: Zero to trace cells



Rapid Resolution

INFLAMMATION REDUCTION FOLLOWING CATARACT SURGERY³

Mean Summed Ocular Inflammation Score (SOIS) at each visit



Pain Free at Day 1

Approximately 4 of 5 patients were pain free at Day 1^{1,2§}

• 78.8% vs 49.5% with vehicle; P<0.0001

DESIGNED FOR COMFORT AND CONVENIENCE

- More physiologic pH^{1,2,4}
- Ocular comfort with convenient QD dosing demonstrated in PROLENSA™-treated eyes^{1,2}
 - Patients reported less foreign body sensation and photophobia, and had less redness vs vehicle²

*Total inflammation was assessed by the SOIS. Complete clearance of inflammation was defined as the proportion of patients who achieved a SOIS of grade 0 (0 cells and absence of flare).²

§Ocular pain was evaluated by the Ocular Comfort Grading Assessment.⁷

Dosage and Administration

Instill one drop into the affected eye once daily beginning 1 day prior to surgery, continued on the day of surgery, and through the first 14 days post surgery.

Adverse Reactions

The most commonly reported adverse reactions in 3%-6% of patients were anterior chamber inflammation, foreign body sensation, eye pain, photophobia, and blurred vision.

PROLENSA™
(bromfenac ophthalmic solution) 0.07%

PROLENSA

Introducing an advanced formulation of BROMDAY® (bromfenac ophthalmic solution) 0.09%

PROLENSA™: Powered for penetration



• Advanced formulation facilitates corneal penetration¹⁻³

• Powered for efficacy

Powerful clearance

- More than twice as many patients achieved complete clearance vs vehicle at Day 15^{1,2}
- 80% of patients had zero to trace cells²

Rapid resolution

- Rapid reduction of inflammation following cataract surgery²

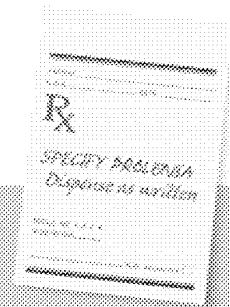
Pain free at Day 1

- Approximately 4 of 5 patients were pain free at Day 1^{1,2}

• Designed for ocular comfort and convenience with QD efficacy^{1,2}

• No shaking required; solution delivers consistent dose in each drop^{1,3}

• Available in 1.6-mL and 3-mL bottle sizes



Sign DISPENSE AS WRITTEN (DAW), DO NOT SUBSTITUTE (DNS), or BRAND MEDICALLY NECESSARY (BMN)*

*Inclusion of BMN required only for certain states, as listed in the National Association of Boards of Pharmacy's Survey of Pharmacy Law.

IMPORTANT RISK INFORMATION ABOUT PROLENSA™

Indications and Usage

PROLENSA™ (bromfenac ophthalmic solution) 0.07% is a nonsteroidal anti-inflammatory drug (NSAID) indicated for the treatment of postoperative inflammation and reduction of ocular pain in patients who have undergone cataract surgery.

Dosage and Administration

Instill one drop into the affected eye once daily beginning 1 day prior to surgery, continued on the day of surgery, and through the first 14 days post surgery.

Please see full Prescribing Information for PROLENSA™ inside pocket.

Warnings and Precautions

- Sulfite allergic reactions
- Slow or delayed healing
- Potential for cross-sensitivity
- Increased bleeding of ocular tissues
- Corneal effects, including keratitis
- Contact lens wear

Adverse Reactions

The most commonly reported adverse reactions in 3%-8% of patients were anterior chamber inflammation, foreign body sensation, eye pain, photophobia, and blurred vision.

References: 1. PROLENSA™ Prescribing Information, April 2013. 2. Data on file: Bausch & Lomb Incorporated. 3. Baklayan GA, Patterson HM, Song CX, Gao JA, McNamee FR. 24-hour evaluation of the ocular distribution of ¹⁴C-labeled bromfenac following topical instillation into the eyes of New Zealand White rabbits. *J Ocul Pharmacol Ther.* 2008;24(4):392-398. 4. Kramer I, Holze M, Durr A. Tissue/solubility requirements for the ophthalmic use of anti-inflammatories. In: Kramer A, Balthasar-Baumann W, eds. *Antiseptic Prophylaxis and Therapy in Ocular Infections: Principles, Clinical Practice and Infection Control*. Vol. 33. Basel, Switzerland: Karger; 2002:96-116. 5. Lang JC, Roehrs HC, Jani R. Ophthalmic preparations. In: *Key BB, ed. Remington, The Science and Practice of Pharmacy*. 21st ed. Philadelphia, PA: Lippincott Williams & Wilkins; 2006:950-979.

©/™ are trademarks of Bausch & Lomb Incorporated or its affiliates.
© 2013 Bausch & Lomb Incorporated. Printed in USA. US/PRO/13/001 4/13

BAUSCH + LOMB

PROLENSA™
(bromfenac ophthalmic solution) 0.07%

CONFIDENTIAL

PROL 0228127

**DOCKET
ALARM**

Find authenticated court documents without watermarks at docketalarm.com.