

Introducing an advanced formulation of BROMDAY<sup>®</sup> (bromfenac ophthalmic solution) 0.07%.

# PROLENSA<sup>™</sup> POWERED FOR PENETRATION

PROLENSA<sup>™</sup> delivers potency and penetration with QD efficacy<sup>1,2</sup>



PROLENSA

## IMPORTANT RISK INFORMATION ABOUT PROLENSA<sup>™</sup>

### Indications and Usage

PROLENSA<sup>™</sup> (bromfenac ophthalmic solution) 0.07% is a non-steroidal and 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<sup>™</sup> 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.

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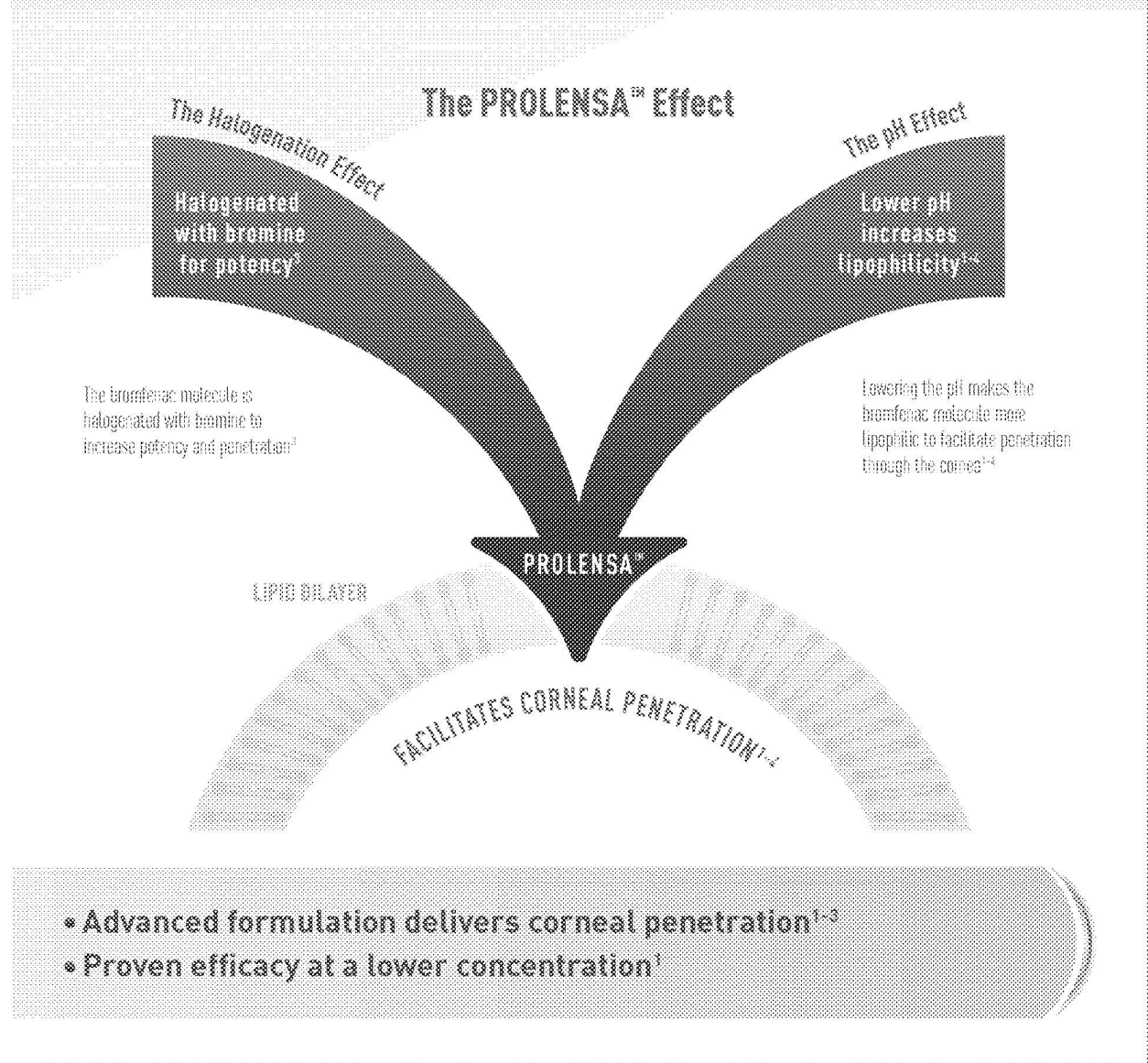
**PROLENSA<sup>™</sup>**  
(bromfenac ophthalmic  
solution) 0.07%

PROL0328434



# PROLENSA™: Powered for penetration

ADVANCING THE FORMULATION TO FACILITATE CORNEAL PENETRATION<sup>1-3</sup>



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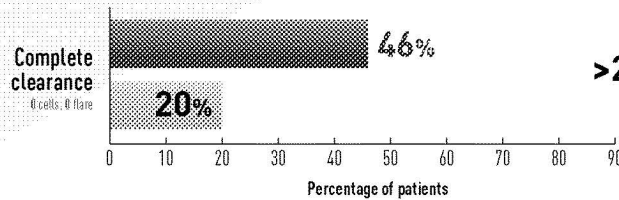
**Study design:** Clinical efficacy evaluated in 2 randomized, double-masked, vehicle-controlled trials of patients undergoing cataract surgery. Each randomized patient received PROLENSA™ or vehicle starting with one drop into surgical eye the day prior to and the day of surgery, and for 14 days post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

# PROLENSA™: Powered for efficacy

## Powerful Clearance

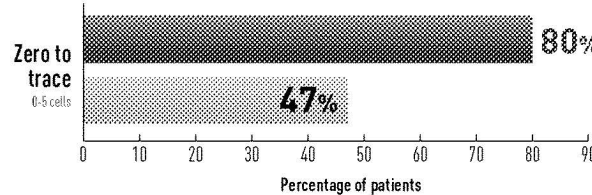
### INFLAMMATION CLEARANCE AT DAY 15<sup>1,2</sup>

Primary endpoint: Complete clearance of cells and flare\*



**>2x** as many patients had complete clearance ( $P < 0.0001$ )

Additional prespecified endpoint: Zero to trace cells

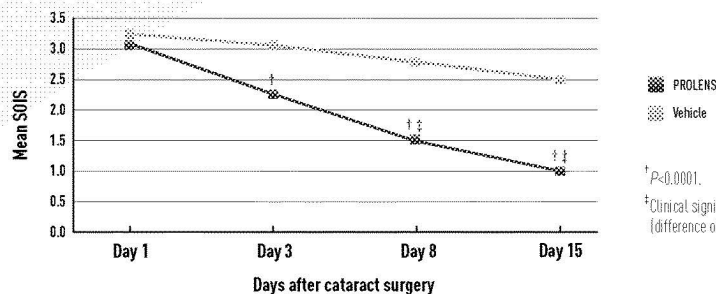


of patients had zero to trace cells ( $P < 0.0001$ )

## Rapid Resolution

### INFLAMMATION REDUCTION FOLLOWING CATARACT SURGERY<sup>7</sup>

Mean Summed Ocular Inflammation Score (SOIS) at each visit



<sup>†</sup> $P < 0.0001$ .

<sup>‡</sup>Clinical significance by Days 8 and 15 (difference of  $>1.0$  in mean SOIS).

## Pain Free at Day 1

Approximately 4 of 5 patients were pain free at Day 1<sup>1,2,8</sup>

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

## DESIGNED FOR COMFORT AND CONVENIENCE

- More physiologic pH<sup>1,2,4</sup>
- Ocular comfort with convenient QD dosing demonstrated in PROLENSA™-treated eyes<sup>1,2</sup>
  - Patients reported less foreign body sensation and photophobia, and had less redness vs vehicle<sup>2</sup>

\*Ocular 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).<sup>1</sup>

<sup>†</sup>Ocular pain was evaluated by the Ocular Comfort Grading Assessment.<sup>7</sup>

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### Adverse Reactions

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# PROLENSA™: Powered for penetration



- Advanced formulation facilitates corneal penetration<sup>1,3</sup>
- Powered for efficacy
  - Powerful clearance
    - More than twice as many patients achieved complete clearance vs vehicle at Day 15<sup>1,2</sup>
    - 80% of patients had zero to trace cells<sup>2</sup>
  - Rapid resolution
    - Rapid reduction of inflammation following cataract surgery<sup>2</sup>
  - Pain free at Day 1
    - Approximately 4 of 5 patients were pain free at Day 1<sup>1,2</sup>

- Designed for ocular comfort and convenience with QD efficacy<sup>1,2</sup>

- No shaking required; solution delivers consistent dose in each drop<sup>1,3</sup>
- 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.

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### 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.

References: 1. PROLENSA™ Prescribing Information, April 2013. 2. Data on file, Bausch & Lomb Incorporated. 3. Baktayan GA, Patterson HM, Song EK, Gow JA, McNewan FM. 24-hour evaluation of the ocular distribution of <sup>14</sup>C-labeled bromfenac following topical instillation into the eyes of New Zealand White rabbits. *J Ocul Pharmacol Ther.* 2008;24(4):392-398. 4. Kramer A, Hsieh M, Drais A. Formulation requirements for the ophthalmic use of anti-inflammatories. In: Kramer A, Gekker S, Baumann W, eds. *Antiseptic Prophylaxis and Therapy in Ocular Infections: Principles, Clinical Practice and Infection Control*. Vol. 33. Basel, Switzerland: Karger, 2002:86-116. 5. Lang JC, Reehrs MC, Jani R. Ophthalmic preparations. In: *Toy DB, ed. Remington: The Science and Practice of Pharmacy*. 21st ed. Philadelphia, PA: Lippincott Williams & Wilkins, 2006:850-970.

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