

# INTRODUCING PROLENSA™ (bromfenac ophthalmic solution) 0.07%

## Powered for penetration



PRODUCT INFORMATION	
<b>NAME AND INDICATION</b>	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
<b>DESCRIPTION</b>	A sterile, topical NSAID for ophthalmic use
<b>FILL SIZES</b>	1.6 mL in a 7.5-mL container and 3 mL in a 7.5-mL container
<b>NDC</b>	1.6 mL {24208-602-01}; 3 mL {24208-602-03}
<b>DELIVERY</b>	Solution
<b>ACTIVE INGREDIENT</b>	Bromfenac
<b>INACTIVE INGREDIENTS</b>	Boric acid, edetate disodium, povidone, sodium borate, sodium sulfite, tyloxapol, sodium hydroxide to adjust pH, and Water for Injection, USP
<b>PRESERVATIVE</b>	Benzalkonium chloride 0.005%
<b>HOW SUPPLIED</b>	White low-density polyethylene (LDPE) plastic squeeze bottle with a 15-mm LDPE dropper tip and a 15-mm polypropylene gray cap
<b>DOSING</b>	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
<b>A/B RATING</b>	There is no A/B bioequivalent for PROLENSA™

PACKAGING SPECIFICATIONS		
<b>STORAGE CONDITIONS</b>	Store at 59°F to 77°F (15°C-25°C)	
<b>SELLING UNIT DIMENSIONS</b>	Fill 5 g	Dimensions 1½" × 1½" × 3½" (L×W×D)
<b>SHIPPING CASE DIMENSIONS</b>	Pack 144	Dimensions 13¾" × 10¾" × 7"

**WITH COUPON, PATIENTS SAVE UP TO \$50 ON PROLENSA™ PRESCRIPTIONS AFTER A MINIMUM \$30 OUT-OF-POCKET EXPENSE\***

PRICING AND ORDER INFORMATION		
<b>Phone orders</b> 1.800.323.0000	<b>Fax orders</b> 1.888.386.1222	<b>Medical Affairs</b> 1.800.227.1427 ext 2040
<b>WAC</b> \$170.63 (either size, same WAC)	<b>NDC</b> 24208-602-01 24208-602-03	

\*TERMS AND CONDITIONS: Patient not eligible if prescriptions are paid in part or full by any state or federally funded programs including but not limited to Medicare or Medicaid, Medicaid, VA, DVA, or TRICARE. MCAZ is not responsible for any transactions processed under this program where Medicaid, Medicare, and Medicaid ("Government Program") payment in part or full has been applied. Only patients who reside in the US or the Commonwealth of Puerto Rico can participate in the PROLENSA™ coupon program. Cash payers are eligible for this program. There are no age restrictions in this program. There are no gender restrictions in this program.

Please see Important Risk Information on reverse.

**PROLENSA™**  
(bromfenac ophthalmic solution) 0.07%



For the treatment of postoperative inflammation and reduction of ocular pain in patients who have undergone cataract surgery

## PROLENSA™: Potency and penetration with QD efficacy<sup>1,2</sup>

### FORMULATED TO FACILITATE CORNEAL PENETRATION

- Advanced formulation delivers corneal penetration<sup>1-3</sup>
- Proven efficacy at a lower concentration than BROMDAY® (bromfenac ophthalmic solution) 0.09%<sup>1,4</sup>

### POWERED FOR EFFICACY

- Powerful clearance—More than twice as many patients achieved complete clearance of postoperative inflammation vs vehicle at Day 15 (45.5% vs 20.2%;  $P < 0.0001$ )<sup>1,2</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 COMFORT AND CONVENIENCE

- Designed for ocular comfort and convenience with QD efficacy<sup>1,2</sup>
- No shaking required; solution delivers consistent dose in each drop<sup>1,5</sup>

Visit [www.bausch.com](http://www.bausch.com)

For product-related questions and concerns, call **1.800.323.0000**.

### 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.

#### 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.

Please see complete information about PROLENSA™ in the accompanying full Prescribing Information.

\*76.9% of PROLENSA™-treated patients were pain free at Day 1 vs 49.5% with vehicle ( $P < 0.0001$ ).<sup>1,2</sup>

References: 1. PROLENSA™ Prescribing Information, April 2013. 2. Data on file, Bausch & Lomb Incorporated. 3. Sukdjan PA, Peterson HM, Sung EK, Gow JA, Millham LR. 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. BROMDAY® Prescribing Information, August 2011. 5. Lung JC, Hoehn RE, Jem R. Ophthalmic preparations. In: Guy BB, ed. *Remington: The Science and Practice of Pharmacy*, 21st ed. Philadelphia, PA: Lippincott Williams & Wilkins; 2004:696-676.

©/™ are trademarks of Bausch & Lomb Incorporated or its affiliates.

All other product/brand names are trademarks of their respective owners.

©2013 Bausch & Lomb Incorporated. Printed in USA US/PRA/13/0052 4/13

**BAUSCH + LOMB**

**PROLENSA™**  
(bromfenac ophthalmic  
solution) 0.07%

**DOCKET  
ALARM**

Find authenticated court documents without watermarks at [docketalarm.com](http://docketalarm.com).