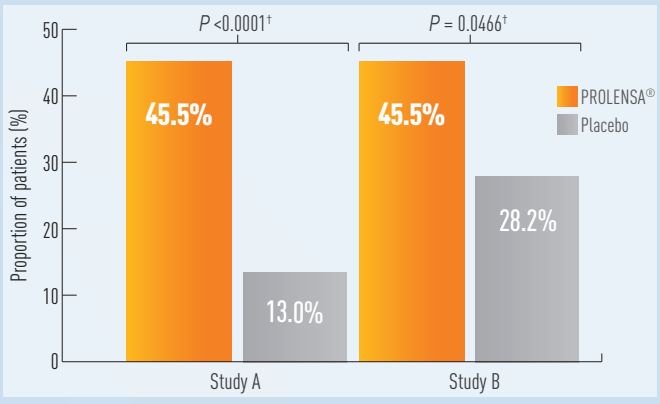
PROLENSA

A once-daily NSAID that reduces inflammation and pain

PROLENSA® (bromfenac ophthalmic solution) 0.07% w/v is indicated for the treatment of postoperative inflammation and reduction of ocular pain in patients who have undergone cataract surgery.

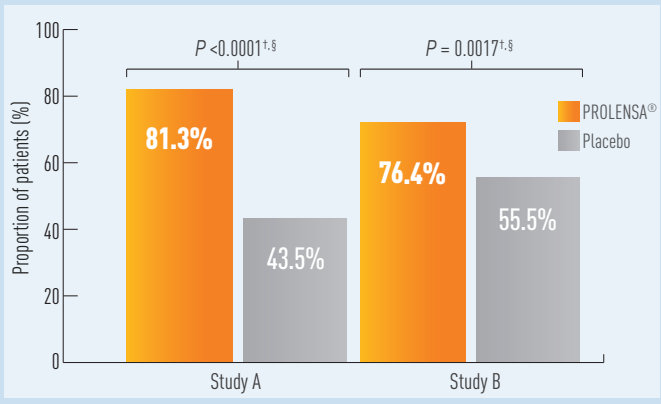
Primary Endpoint: Demonstrated Reduction of Inflammation

Approximately 45.5% of patients had complete clearing of ocular inflammation (anterior chamber cells and flare)* following cataract surgery at Postoperative Day 15.[1]



Secondary Endpoint: Demonstrated Pain Reduction

Approximately 4 of 5 patients were pain free‡ following cataract surgery at Day 1.[1]



Features of PROLENSA®:**

An NSAID
- The only bromfenac ophthalmic solution in Canada[2]

Advanced formulation facilitates penetration through the cornea
- PROLENSA® inhibits COX-1 and COX-2[1,3-4]

Drug distributed uniformly
- Bromfenac is extensively distributed throughout the eye (in animal studies)[1]

Close to pH of human tears (7.4)[1,2,5]
- PROLENSA® has a pH of 7.8[1,2]

Convenient once-daily dosing[1]
- No shaking required[2]

DO YOU HAVE INVENTORY?

Product	Size	B+L SKU#
PROLENSA	3 mL	AC49405

UPC Code	List Price per Unit
3 24208 60203 4	$23.00

Wholesale Order Numbers	
Kohl & Frisch 153522	McKesson 84425

Pharmacy Order Numbers
Shoppers Drug Mart 3 24208 60203 4

To order, please contact your preferred Distribution Centre, Wholesaler, or Bausch + Lomb Customer Service at 1-800-686-7720.

Indications and clinical use:

PROLENSA® (bromfenac ophthalmic solution) 0.07% w/v is indicated for the treatment of postoperative inflammation and reduction of ocular pain in patients who have undergone cataract surgery.
- The safety and efficacy of PROLENSA® has not been studied in pediatric patients (<18 years of age) and should not be used in these populations.

Contraindications:
- Hypersensitivity to PROLENSA® or any ingredient in the formulation or component of the container.
- There is the potential for cross-sensitivity for those whose acute asthmatic attacks, urticaria, rhinitis or other allergic manifestations are precipitated by acetylsalicylic acid (ASA) or other nonsteroidal anti-inflammatory agents.

Relevant warnings and precautions:
- There is the potential for cross-sensitivity to acetylsalicylic acid, phenylacetic acid derivatives, and other NSAIDs, including PROLENSA®; caution should be used when treating those who have previously exhibited sensitivities to these drugs.
- All topical NSAIDs may result in keratitis, which could be sight threatening; it may also slow or delay healing, and may cause increased bleeding of ocular tissues in conjunction with ocular surgery.
- The use of NSAIDs after cataract surgery may delay wound healing.
- PROLENSA® contains sodium sulfite, which may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people.
- Should not be used in pregnant or lactating women unless the benefit to the mother clearly outweighs the risk to the infant/child.
- PROLENSA® should not be instilled while wearing contact lenses.

For more information:

Consult the Product Monograph at **http://www.bausch.ca/Portals/59/Files/Monograph/Pharma/Prolensa-PM-ca-en.pdf** for contraindications, warnings, precautions, adverse reactions, interactions, dosing, and conditions of clinical use.
The Product Monograph is also available by calling 1-888-459-5000.

* Postoperative inflammation was judged by the complete resolution of anterior chamber cells and flare at Postoperative Day 15 (i.e., cell count 0 and no flare).[1]

† In two phase III, randomized, multicentre, double-masked, parallel-group, 4-week trials, clinical safety and efficacy evaluations of PROLENSA® vs. placebo were conducted for the treatment of inflammation and pain following cataract surgery (Study A, N = 220;Study B, N = 220).

‡ Pain free was defined as having grade 0 (no) pain at Postoperative Day 1.[1]

§ P-value for PROLENSA® vs. placebo was from a Fisher's exact test.

** Comparative clinical significance unknown.

ASA = acetylsalicylic acid; COX-1 = cyclooxygenase 1; COX-2 = cyclooxygenase 2; NSAID = nonsteroidal anti-inflammatory drug

References:
1. PROLENSA® (bromfenac ophthalmic solution 0.07%) Product Monograph. Bausch & Lomb Canada Inc., February 8, 2017.
2. Bausch & Lomb Canada Inc. Medical Letter. Data on file. August 14, 2015.
3. Baklayan GA, Muñoz M. The ocular distribution of 14C-labelled bromfenac ophthalmic solution 0.07% in a rabbit model. *Clin Ophthalmol* 2014;8:1717–1724.
4. Silverstein SM, Jackson MA, Goldberg DF, et al. The efficacy of bromfenac ophthalmic solution 0.07% dosed once daily in achieving zero-to-trace anterior chamber cell severity following cataract surgery. *Clin Ophthalmol* 2014;8:965–972.
5. Scott AS, Fong E. *Body Structures and Function.* 12th Ed. USA: Delmar CENGAGE Learning, 2014.

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PAAB

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