Postop Communication and Pull-through with Cataract Patients and Pharmacists

Cathleen McCabe, MD and I. Paul Singh, MD

Since its FDA approval in 1997, PROLENSA® (bromfenac ophthalmic solution) 0.07% has become an integral part of our treatment of postoperative inflammation and reduction of ocular pain in patients who have undergone cataract surgery.[1]

Patient adherence to the drug regimen we prescribe after cataract surgery is important to positive outcomes.[2] Adherence rates are clearly impacted by whether prescriptions are filled and taken as prescribed, which includes the drug's dosing schedule.[3] Other factors may impact adherence rates, such as the patient's understanding of the drug's importance to healing.[2,4]

We have addressed these issues in our practices by implementing a clear process to communicate to patients and pharmacists

Please see Full Prescribing Information for PROLENSA® on pages 7 and 8.

why we have prescribed PROLENSA®—for which there is no generic equivalent—and to emphasize our desire to have prescriptions filled as written and taken as prescribed. Here, we discuss how once-daily PROLENSA® fits into our management of postop inflammation and pain in cataract patients and the steps we have taken to make sure patients get the medications we prescribe.

CONTROLLING PAIN AND INFLAMMATION AFTER CATARACT SURGERY

Although advanced surgical techniques have made cataract surgery less invasive and traumatic, pharmaceutical control of postoperative pain and inflammation remains an important element in the treatment process.[5]

Our job as surgeons requires that we control inflammation, which can cause tissue damage and impede healing.[6] Inflammation typically begins at the time we start the surgical procedure and continues afterwards.[6]

Our job as surgeons also demands that we make surgery as painless as possible to give patients a positive experience. In addition, patients often judge the quality of their surgery—and one's skill as a surgeon—by the amount of pain they experience.

PROLENSA®: OUR NSAID OF CHOICE FOR POST-CATARACT SURGERY PATIENTS

Advances have been made to help address patients' ocular comfort. The use of nonsteroidal anti-inflammatory drugs (NSAIDs) after cataract surgery has been shown to reduce postoperative pain and inflammation.[2]

NSAIDs work by inhibiting cyclooxygenase (COX) at the site of inflammation. Inhibiting COX reduces inflammation by acting on the arachidonic acid pathway to inhibit the production of prostaglandins.[2] NSAIDs act at later stages in the arachidonic acid pathway than corticosteroids but can achieve similar anti-inflammatory effects.[2]

WHY PROLENSA®?

- The only branded formulation of bromfenac approved for once-daily use[1]
- Halogenated with bromine and pH of 7.8 to increase potency and corneal penetration[2]
- Convenient once-daily dosing with no shaking required[1]
- Established efficacy and safety profile[7]
- Manufactured in an FDA-approved facility that helps ensure stringent safety and quality control
- No generic equivalent available
- Bausch + Lomb is committed to providing access to PROLENSA® for your eligible patients whether they are eligible insured, eligible uninsured, or on Medicare Part D*

*Terms and conditions apply.

We prefer to use a once-daily branded bromfenac-containing drop such as PROLENSA® as our NSAID of choice. We have chosen PROLENSA® for a number of reasons, including its established efficacy and safety profile and convenient once-daily dosing, and for meeting our patients' ocular comfort needs. (See box, "Why PROLENSA®?)

We have chosen PROLENSA® for a number of reasons, including its established efficacy and safety profile and convenient once-daily dosing, and for meeting our patients' ocular comfort needs.

Two phase 3, prospective, randomized, double-masked, placebo-controlled clinical trials of PROLENSA® were conducted at 39 ophthalmology clinics in the US. Subjects were

randomized to receive either bromfenac 0.07% or placebo, dosed once daily. When data from the two trials were pooled (440 study eyes: 222 in the bromfenac group and 218 in the placebo group), it was found that the proportion of subjects who had 0 to trace cells at Day 15 was significantly higher in the PROLENSA® group than in the vehicle group ($P < 0.0001$). (Figure 1).[7]

In addition, a significantly greater proportion of subjects were pain free in the PROLENSA® group than in the vehicle group at Day 1, and this continued through the remaining follow-up visits ($P < 0.0001$).[7]

Patients who received PROLENSA® also reported less foreign body sensation, photophobia, and redness vs those treated with vehicle.[8]

There is no generic equivalent of PROLENSA®. Unfortunately, pharmacists will sometimes recommend or encourage a switch to another medication, which may be a generic, for the branded product we prescribe. In our experience, patients are sometimes unaware that different medications may have different dosing schedules or shaking requirements.

ALIGNING THE PRACTICE

Before developing effective, consistent strategies for communicating with patients and pharmacists, it is helpful to have all stakeholders in the practice agree to protocols, including uniform medication choices for routine procedures. In both our practices, we made these decisions collaboratively in meetings with our ophthalmologists and management teams. This decision-making process increases buy-in and consistency and makes it easier to ensure that patients are following their postoperative medication course. Our practices' cataract protocols include PROLENSA® as our NSAID of choice to manage postop pain and inflammation.

Our choice of this branded NSAID was guided by the fact that modern cataract patients have high expectations for cataract surgery to improve their quality of vision.[9] These expectations are even greater with premium refractive lens patients, who bear some of the cost of these technologies.

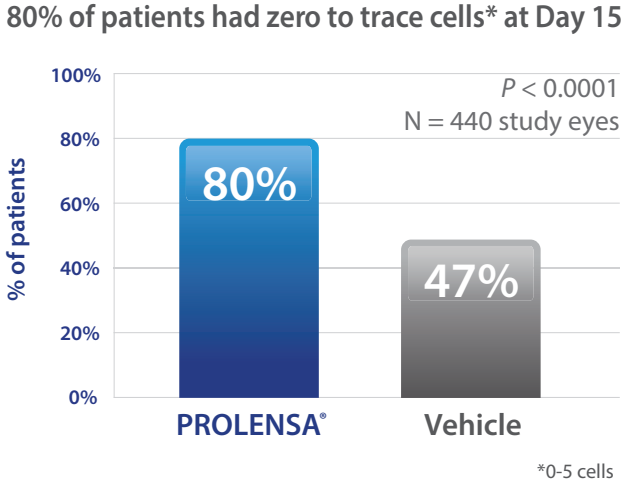

FIGURE 1 STUDY DESIGN: Clinical efficacy evaluated in two randomized, double-masked, vehicle-controlled trials of patients undergoing cataract surgery. Each randomized patient received PROLENSA® or vehicle starting with one drop into the surgical eye the day prior to and the day of surgery, and for 14 days post-surgery.

As a result of patient expectations, we try to tightly control every aspect of surgery. We take extensive preoperative measurements, optimize the patient's ocular surface, and make sure the axis of cylinder is perfect. Why wouldn't we bring the same level of deliberation to our choice of NSAIDs?

Our goal with cataract surgery is not simply 20/20 vision; it is to provide a positive patient experience—before, during, and after surgery. The patient experience includes how the patient was treated at the preop consult, whether the patient was adequately educated about what to expect with the procedure, and the patient's ocular comfort following surgery.

We prescribe drops to control postop pain and inflammation while striving to meet our patients' ocular comfort needs. If a patient comes away with a negative memory of the experience—and that includes the surgery and medication—that patient may be less likely to recommend us to friends and family. In both our practices, we aim to choose drops that are comfortable on the eye upon instillation, that are

dosed conveniently once a day, and that come in a bottle that doesn't need to be shaken in order to provide dose uniformity. All of these criteria are filled by PROLENSA®.[1]

EDUCATING COLLEAGUES AND STAFF

Once our practices were aligned in regard to the postop protocol, we were able to educate colleagues and staff on the key components of our drug selection rationale: clinical outcomes; the quality, consistency, and safety profile of the drug; and dosing and tolerability.

The lead surgeon's passion for and communication of medication choice can be imparted to colleagues—for example, at monthly meetings, which can be used to reaffirm the consensus around protocols, review the rationale for drug selection, and ask colleagues to share their experience with the chosen medications.

Practice-wide meetings are another way to reaffirm staff commitment to postop protocols. These can be a great opportunity to show employees that they are valued and to educate them on topics such as the reasoning behind preferred medication choice.

Different ophthalmic NSAIDs may not be interchangeable; and there is no generic equivalent to PROLENSA®.

As the result of educating colleagues and staff on the rationale behind medication choice, we have found that we receive far fewer call backs from pharmacies. Call backs can take up an inordinate amount of staff time and resources.

COMMUNICATION WITH PATIENTS

With the availability of a variety of ophthalmic NSAIDS, including generic medications, we believe it is important to educate and empower patients—many of whom are cost-conscious—about why we prescribe PROLENSA®.

We both prefer to prescribe branded drops. In particular, we prefer PROLENSA® for the treatment of post-surgical pain and inflammation in cataract patients because it is approved for once-daily use and does not require shaking,[1] is halogenated with bromine and has a pH of 7.8 to increase potency and corneal penetration,[2] and is manufactured in an FDA-approved facility that helps ensure stringent safety and quality control.

Importantly, different ophthalmic NSAIDs may not be interchangeable; and there is no generic equivalent to PROLENSA®.

Dr. Singh provides a printed handout to patients outlining some of the important reasons he chooses a branded NSAID like PROLENSA®. Dr. McCabe holds a brief (20-minute) postop class during which the medical services director carefully reviews the instructions for postop care and provides patients and caregivers with a handout that shows the bottles of the medications they have been prescribed and their dosing schedules.

We let patients know that we want to control as much of the surgery and postoperative course as possible. We might say something like, "If I were having this once-in-a-lifetime surgery, or someone in my family was, these are the drops I would prescribe."

SAMPLE MESSAGES

Some of the messages that we have found useful in communicating the value of branded NSAIDs to patients include:

- I have chosen this medication for you because this is a once-in-a-lifetime surgery—maybe twice if you have a cataract in the other eye as well—as well as a significant investment
- I have chosen this medication because of its efficacy and safety profile
- This medication only needs to be used once a day

PROLENSA® is manufactured in an FDA-approved facility, which helps ensure the quality, consistency, and safety profile of this medication.

The way we talk to patients about drug selection must be consistent throughout the practice and delivered by multiple people at multiple points in the patient journey. (See box, "Sample Messages.") What the ophthalmologist says must reflect what is said by the comanaging optometrist, the surgical coordinator, the technician, and the front office staff. Consistency and repetition help increase the likelihood of correct medication fulfillment and use by the patient.

In addition to consistency, details around choice of medication must be delivered with conviction and contain the right level of detail. For example, in our practices, we don't proactively discuss in detail every aspect of the clinical data that supports our choice of NSAID, but we are always prepared to share that data if patients ask.

We let patients know that we want to control as much of the surgery and postoperative course as possible. We might say something like, "If I were having this once-in-a-lifetime surgery, or someone in my family was, these are the drops I would prescribe."

In our experience, educated patients are empowered patients and are therefore more likely to obtain the medications we prescribe. Branded drug fulfillment can be stymied by the pharmacy if patients have no ability to explain why the prescription should be dispensed as written. Preparing patients for their interaction at the pharmacy has two major components.

First, patients need to know that they may be offered a different drug than prescribed and told by the pharmacist that it is the same as the branded drug but costs less. In response, we make sure patients understand that we have prescribed PROLENSA® because of its efficacy and safety profile, and that it has no generic equivalent. Second, patients should be informed before they visit the pharmacy about the cost of their medication in order to avoid "sticker shock." This decreases the chance that the office will receive a call back asking about generic substitutions.

Patient-savings programs are a good complement to NSAID education for cost-conscious patients. For the occasional patients who truly cannot afford branded NSAIDs, we provide samples of branded NSAIDs.

COMMUNICATION WITH PHARMACISTS

It's important to recognize that pharmacies may take the choice of NSAID out of the physician's hands.

In both of our practices, we have communicated our post-treatment protocol preferences to local pharmacies to help ensure that the prescription will be filled as written. As is common in the pharmacy setting, pharmacist rotation can impact our post-cataract surgery treatment protocol preferences.

That's one of the reasons it's so important to educate our patients about why we have prescribed branded ophthalmic NSAIDs and to prepare them for having a conversation with the pharmacist about price and the availability of patient-savings programs. We have found that pharmacists sometimes will not process patient savings cards unless the patient insists.

IN CONCLUSION

The perception among some ophthalmologists is that communicating with patients about why they choose branded NSAIDs takes too much time. In our practices, we use scribes to assist with note-taking, which frees up several minutes that would have been taken up documenting the visit in the patient's chart.

Ultimately, we find that delivering a short set of consistent messages only takes 2 or 3 extra minutes of the ophthalmologist's time and can save hours of dealing with pharmacy call backs, and may help ensure a more positive patient experience at the pharmacy in the long run. When those messages are reinforced at all levels of the practice, it is possible to ensure that patients get PROLENSA® and the other

medications we prescribe—with the ultimate aim of getting positive outcomes from their cataract procedures.

REFERENCES

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Cathleen McCabe, MD, is medical director of The Eye Associates, Sarasota, FL, co-chair for the cataract section of the American Academy of Ophthalmology's Practicing Ophthalmologist Curriculum, and president of Cedars/ASPENS, a group of anterior segment and corneal specialists. Dr. McCabe is a paid consultant for Bausch & Lomb.

I. Paul Singh, MD, is president of The Eye Centers of Racine & Kenosha, Ltd. He was the first surgeon in Wisconsin to implant the iStent and XEN gel stent for glaucoma, was instrumental in bringing laser-assisted cataract surgery to the state, and has developed tools specifically for small-incision cataract surgery. Dr. Singh is a paid consultant for Bausch & Lomb.

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BAUSCH + LOMB

PROLENSA

(bromfenac ophthalmic solution) 0.07%

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use PROLENSA® (bromfenac ophthalmic solution) 0.07% safely and effectively. See full prescribing information for PROLENSA ophthalmic solution.

PROLENSA (bromfenac ophthalmic solution) 0.07%

Initial U.S. Approval: 1997

----------INDICATIONS AND USAGE ----------

PROLENSA 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. (1)

---------- 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. (2.1)

---------- DOSAGE FORMS AND STRENGTHS ----------

Topical ophthalmic solution: bromfenac 0.07% (3)

----------CONTRAINDICATIONS ----------

None (4)

---------- WARNINGS AND PRECAUTIONS ----------

- Sulfite Allergic Reactions (5.1)
- Slow or Delayed Healing (5.2)
- Potential for Cross-Sensitivity (5.3)
- Increase bleeding of ocular tissues (5.4)
- Corneal effects including keratitis (5.5)
- Contact Lens Wear (5.6)

---------- ADVERSE REACTIONS ----------

The most commonly reported adverse reactions in 3 to 8% of patients were anterior chamber inflammation, foreign body sensation, eye pain, photophobia, and vision blurred. (6.1).

To report SUSPECTED ADVERSE REACTIONS, contact Bausch + Lomb, a division of Valeant Pharmaceuticals North America LLC, at 1-800-321-4576 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 6/2016

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

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

2 DOSAGE AND ADMINISTRATION

2.1 Recommended Dosing

One drop of PROLENSA ophthalmic solution should be applied to the affected eye once daily beginning 1 day prior to cataract surgery, continued on the day of surgery, and through the first 14 days of the postoperative period.

2.2 Use with Other Topical Ophthalmic Medications

PROLENSA ophthalmic solution may be administered in conjunction with other topical ophthalmic medications such as alpha-agonists, beta-blockers, carbonic anhydrase inhibitors, cycloplegics, and mydriatics. Drops should be administered at least 5 minutes apart.

3 DOSAGE FORMS AND STRENGTHS

Topical ophthalmic solution: bromfenac 0.07%

4 CONTRAINDICATIONS

None

5 WARNINGS AND PRECAUTIONS

5.1 Sulfite Allergic Reactions

Contains sodium sulfite, a sulfite that may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than in non-asthmatic people.

5.2 Slow or Delayed Healing

All topical nonsteroidal anti-inflammatory drugs (NSAIDs), including bromfenac, may slow or delay healing. Topical corticosteroids are also known to slow or delay healing. Concomitant use of topical NSAIDs and topical steroids may increase the potential for healing problems.

5.3 Potential for Cross-Sensitivity

There is the potential for cross-sensitivity to acetylsalicylic acid, phenylacetic acid derivatives, and other NSAIDs, including bromfenac. Therefore, caution should be used when treating individuals who have previously exhibited sensitivities to these drugs.

5.4 Increased Bleeding Time

With some NSAIDs, including bromfenac, there exists the potential for increased bleeding time due to interference with platelet aggregation. There have been reports that ocularly applied NSAIDs may cause increased bleeding of ocular tissues (including hyphemas) in conjunction with ocular surgery.

It is recommended that PROLENSA ophthalmic solution be used with caution in patients with known bleeding tendencies or who are receiving other medications which may prolong bleeding time.

5.5 Keratitis and Corneal Reactions

Use of topical NSAIDs may result in keratitis. In some susceptible patients, continued use of topical NSAIDs may result in epithelial breakdown, corneal thinning, corneal erosion, corneal ulceration or corneal perforation. These events may be sight threatening. Patients with evidence of corneal epithelial breakdown should immediately discontinue use of topical NSAIDs, including bromfenac, and should be closely monitored for corneal health.

Post-marketing experience with topical NSAIDs suggests that patients with complicated ocular surgeries, corneal denervation, corneal epithelial defects, diabetes mellitus, ocular surface diseases (e.g., dry eye syndrome), rheumatoid arthritis, or repeat ocular surgeries within a short period of time may be at increased risk for corneal adverse events which may become sight threatening. Topical NSAIDs should be used with caution in these patients.

Post-marketing experience with topical NSAIDs also suggests that use more than 24 hours prior to surgery or use beyond 14 days post-surgery may increase patient risk for the occurrence and severity of corneal adverse events.

5.6 Contact Lens Wear

PROLENSA should not be instilled while wearing contact lenses. Remove contact lenses prior to instillation of PROLENSA. The preservative in PROLENSA, benzalkonium chloride, may be absorbed by soft contact lenses. Lenses may be reinserted after 10 minutes following administration of PROLENSA.

6 ADVERSE REACTIONS

6.1 Clinical Trial Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

The most commonly reported adverse reactions following use of PROLENSA following cataract surgery include: anterior chamber inflammation, foreign body sensation, eye pain, photophobia, and vision blurred. These reactions were reported in 3 to 8% of patients.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Treatment of rats at oral doses up to 0.9 mg/kg/day (systemic exposure 90 times the systemic exposure predicted from the recommended human ophthalmic dose [RHOD] assuming the human systemic concentration is at the limit of quantification) and rabbits at oral doses up to 7.5 mg/kg/day (150 times the predicted human systemic exposure) produced no treatment-related malformations in reproduction studies. However, embryo-fetal lethality and maternal toxicity were produced in rats and rabbits at 0.9 mg/kg/day and 7.5 mg/kg/day, respectively. In rats, bromfenac treatment caused delayed parturition at 0.3 mg/kg/day (30 times the predicted human exposure), and caused dystocia, increased neonatal mortality and reduced postnatal growth at 0.9 mg/kg/day.

There are no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Because of the known effects of prostaglandin biosynthesis-inhibiting drugs on the fetal cardiovascular system (closure of ductus arteriosus), the use of PROLENSA ophthalmic solution during late pregnancy should be avoided.

8.3 Nursing Mothers

Caution should be exercised when PROLENSA ophthalmic solution is administered to a nursing woman.

8.4 Pediatric Use

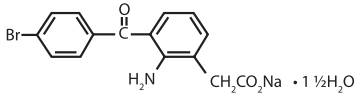
Safety and efficacy in pediatric patients below the age of 18 years have not been established.

8.5 Geriatric Use

There is no evidence that the efficacy or safety profiles for PROLENSA differ in patients 70 years of age and older compared to younger adult patients.

11 DESCRIPTION

PROLENSA (bromfenac ophthalmic solution) 0.07% is a sterile, topical, nonsteroidal anti-inflammatory drug (NSAID) for ophthalmic use. Each mL of PROLENSA contains 0.805 mg bromfenac sodium sesquihydrate (equivalent to 0.7 mg bromfenac free acid). The USAN name for bromfenac sodium sesquihydrate is bromfenac sodium. Bromfenac sodium is designated chemically as sodium [2-amino-3-(4-bromobenzoyl) phenyl] acetate sesquihydrate, with an empirical formula of $C_{15}H_{11}BrNNaO_3 \cdot 1\frac{1}{2}H_2O$. The chemical structure for bromfenac sodium sesquihydrate is:



Bromfenac sodium is a yellow to orange crystalline powder. The molecular weight of bromfenac sodium is 383.17. PROLENSA ophthalmic solution is supplied as a sterile aqueous 0.07% solution, with a pH of 7.8. The osmolality of PROLENSA ophthalmic solution is approximately 300 mOsmol/kg.

Each mL of PROLENSA ophthalmic solution contains:
Active: Each mL contains bromfenac sodium sesquihydrate 0.0805%, which is equivalent to bromfenac free acid 0.07%.
Preservative: benzalkonium chloride 0.005%
Inactives: boric acid, edetate disodium, povidone, sodium borate, sodium sulfite, tyloxapol, sodium hydroxide to adjust pH and water for injection, USP.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Bromfenac is a nonsteroidal anti-inflammatory drug (NSAID) that has anti-inflammatory activity. The mechanism of its action is thought to be due to its ability to block prostaglandin synthesis by inhibiting cyclooxygenase (COX) 1 and 2. Prostaglandins have been shown in many animal models to be mediators of certain kinds of intraocular inflammation. In studies performed in animal eyes, prostaglandins have been shown to produce disruption of the blood-aqueous humor barrier, vasodilation, increased vascular permeability, leukocytosis, and increased intraocular pressure.

12.3 Pharmacokinetics

The plasma concentration of bromfenac following ocular administration of 0.07% PROLENSA (bromfenac ophthalmic solution) in humans is unknown. Based on the maximum proposed dose of one drop to each eye (0.035 mg) and PK information from other routes of administration, the systemic concentration of bromfenac is estimated to be below the limit of quantification (50 ng/mL) at steady-state in humans.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term carcinogenicity studies in rats and mice given oral doses of bromfenac up to 0.6 mg/kg/day (systemic exposure 30 times the systemic exposure predicted from the recommended human ophthalmic dose [RHOD] assuming the human systemic concentration is at the limit of quantification) and 5 mg/kg/day (340 times the predicted human systemic exposure), respectively, revealed no significant increases in tumor incidence.

Bromfenac did not show mutagenic potential in various mutagenicity studies, including the reverse mutation, chromosomal aberration, and micronucleus tests.

Bromfenac did not impair fertility when administered orally to male and female rats at doses up to 0.9 mg/kg/day and 0.3 mg/kg/day, respectively (systemic exposure 90 and 30 times the predicted human exposure, respectively).

14 CLINICAL STUDIES

14.1 Ocular Inflammation and Pain

Bromfenac 0.07% QD for the treatment of postoperative inflammation and reduction of ocular pain was evaluated in two multi-center, randomized, double-masked, parallel-group and placebo (vehicle)-controlled studies. Patients undergoing cataract surgery self-administered bromfenac 0.07% or vehicle once daily, beginning 1 day prior to surgery, continuing on the morning of surgery and for 14 days after surgery. Complete clearance of ocular inflammation (0 cell and no flare) was assessed on Days 1, 3, 8 and 15 post-surgery using slit lamp biomicroscopy. The pain score was self-reported. The primary efficacy endpoint was the proportion of subjects who had complete clearance of ocular inflammation by Day 15. In the intent-to-treat analyses from both assessments, complete clearance at Day 8 and Day 15, bromfenac 0.07% was superior to vehicle as shown in the following table.

Proportion of Subjects with Cleared Ocular Inflammation (0 cells and no flare)				
Study	Visit	Bromfenac 0.07%	Vehicle	Difference (%) (Asymptotic 95% CI)
Study 1	At Day 8	27/112 (24.1%)	7/108 (6.5%)	17.6 (8.4, 26.8)
	At Day 15	51/112 (45.5%)	14/108 (13.0%)	32.5 (21.4, 43.8)
Study 2	At Day 8	33/110 (30.0%)	14/110 (12.7%)	17.3 (6.7, 27.9)
	At Day 15	50/110 (45.5%)	30/110 (27.3%)	18.2 (5.7, 30.7)
Proportion of Subjects Who Were Pain Free				
Study	Visit	Bromfenac 0.07%	Vehicle	Difference (%) (Asymptotic 95% CI)
Study 1	At Day 1	91/112 (81.3%)	47/108 (43.5%)	37.7 (25.9, 49.6)
Study 2	At Day 1	84/110 (76.4%)	61/110 (55.5%)	20.9 (8.7, 33.1)

16 HOW SUPPLIED/STORAGE AND HANDLING

PROLENSA (bromfenac ophthalmic solution) 0.07% is supplied in a white LDPE plastic squeeze bottle with a 15 mm LDPE white dropper tip and 15 mm polypropylene gray cap as follows:

- 1.6 mL in a 7.5 mL container (NDC 24208-602-01)
- 3 mL in a 7.5 mL container (NDC 24208-602-03)

Storage: Store at 15° – 25°C (59° – 77°F).

17 PATIENT COUNSELING INFORMATION

Slowed or Delayed Healing

Advise patients of the possibility that slow or delayed healing may occur while using NSAIDs.

Sterility of Dropper Tip

Advise patients to replace bottle cap after using and to not touch dropper tip to any surface, as this may contaminate the contents.

Advise patients that a single bottle of PROLENSA be used to treat only one eye.

Concomitant Use of Contact Lenses

Advise patients to remove contact lenses prior to instillation of PROLENSA. The preservative in PROLENSA, benzalkonium chloride, may be absorbed by soft contact lenses. Lenses may be reinserted after 10 minutes following administration of PROLENSA.

Concomitant Topical Ocular Therapy

If more than one topical ophthalmic medication is being used, the medicines should be administered at least 5 minutes apart.

Manufactured by:
Bausch + Lomb, a division of Valeant Pharmaceuticals North America LLC, Bridgewater, NJ 08807 USA

Under license from
Senju Pharmaceutical Co., Ltd.
Osaka, Japan 541-0046

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