**SPENDING MORE TIME TALKING TO PHARMACISTS THAN TALKING TO PATIENTS?**

**DR. MITCH JACKSON SHARES HINTS ON HOW TO HELP MINIMIZE CUMBERSOME CALLBACKS AND HELP ENSURE PATIENTS GET THE MEDICATION THEY WERE PRESCRIBED**

**BY MITCHELL A. JACKSON, MD**

Cataract surgery is a once-in-a-lifetime event—our patients invest in this procedure because they see it as a way to improve their quality of life. As eye care professionals, we also know how essential postoperative care is to the overall patient experience. After patients have surgery, you need to remind them they must follow the post-surgery care instructions carefully, which includes filling all medications as prescribed. You’ll want to remind them there are several programs available that may help them access medications that may otherwise be out of their financial reach.

As you know, following cataract surgery, patients will need a medication for the ocular pain they’ve felt and the inflammation they’ll experience. One drug I commonly prescribe is PROLENSA® (bromfenac ophthalmic solution) 0.07%. It’s important to make time to talk with your patients about this treatment so they know what to expect. When you’re talking to patients about this medication, these are some of the points you should touch on.

I remind them of the investment they made in their eyesight by getting cataract surgery.

**Why PROLENSA®?**

Many patients may ask why they were prescribed PROLENSA®. As we know, PROLENSA® has a proven efficacy and safety profile.1,2 It’s why it’s used as a post-cataract surgery medication. Understanding that the patient will usually be taking multiple medications, you may want to explain to them that PROLENSA® is administered as a single drop, once daily. If patients are using more than one topical eye medication, each medication should be administered at least 5 minutes apart.

Sometimes a patient will ask if they can get the generic version of PROLENSA® because it’s cheaper. You should let those patients know that there is no generic equivalent of PROLENSA® and that this particular medicine was prescribed to them for important reasons.

As we know, some pharmacists will call wanting to substitute PROLENSA® for another generic NSAID because of cost to the patient. Tell the pharmacist that the eye doctor has prescribed this particular NSAID, PROLENSA®, for important reasons and that no substitution is allowed.

**Treatment costs**

Whether a patient is insured through commercial insurance, Medicare Part D or even uninsured, Bausch and Lomb has a solution to help eligible patients with their co-pays. I provide a detailed explanation of what plan may work best for them while they’re in my office.

Commercial and eligible uninsured patients may obtain information about these co-pay card programs from their doctor or online at www.bauschchacesprogram.com.

Patients may find simple instructions on this website about how to access and use the co-pays. The cards may reduce co-pays as little as $35 for qualified patients.

Similar benefits are available to those who are insured under Medicare Part D. Fliers with information about the Medicare Part D benefits and associated eligibility criteria are available to distribute to patients; the fliers direct patients to a website where a simple qualification process is available.

If you are speaking to a patient who is not covered by insurance, remind them that this medication, despite its potentially high out-of-pocket cost, is important to their post-cataract surgery recovery process. If patients have any other questions about PROLENSA® savings and assistance programs, tell them to call Bausch + Lomb at 1-800-704-5160 (8:00 AM – 7:00 PM EST, Monday – Sunday).

**Product features**

If a patient asks you about whether or not PROLENSA® works, there are some side effects or how to use the drops, you should tell them the following:

- **On the first day of use,** approximately 4 of 5 patients who used PROLENSA® had pain.1,2 PROLENSA® rapidly reduced inflammation versus placebo after cataract surgery; significant results were seen at Day 1, Day 7, and Day 15.2 Individual results may vary.

If a patient has not been prescribed PROLENSA® because their eyesight is intact, it’s cheaper. You should let those patients know that the eye doctor has prescribed this particular NSAID, PROLENSA®, for important reasons and that no substitution is allowed.

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If you are speaking to a patient who is not covered by insurance, remind them that this medication, despite its potentially high out-of-pocket cost, is important to their post-cataract surgery recovery process. If patients have any other questions about PROLENSA® savings and assistance programs, tell them to call Bausch + Lomb at 1-800-704-5160 (8:00 AM – 7:00 PM EST, Monday – Sunday).

**Product features**

If a patient asks you about whether or not PROLENSA® works, there are some side effects or how to use the drops, you should tell them the following:

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- **1 drop is dropped into the affected eye beginning 1 day before surgery, once on the day of surgery, and once a day for 2 weeks after surgery.**1
- **You do not need to shake the bottle before using it; you will get the same amount of medication in every drop.**3
- **This product is in a 3-mL bottle so in case you accidentally miss your eye when putting in your drops, there is enough product in the bottle to last the entire course of therapy.**
- **The most common side effects (seen in 3%-8% of patients) are inflammation of the front of the eye, foreign body sensation, eye pain, light sensitivity and blurred vision.**1,2

**Patient counseling information**

Advise patients of the following information:

- **It is possible that slow or delayed healing may occur while using NSAIDs such as PROLENSA.**
- **Replace the bottle cap after using and do not let the dropper tip touch any surface, as this may contaminate the contents.**
- **A single bottle of PROLENSA® can be used to treat only one eye.**
- **Contact lenses should be removed before using PROLENSA®.** The preservative in PROLENSA®, benzalkonium chloride, may be absorbed by soft contact lenses.
- **You can reinset lenses 10 minutes after administering PROLENSA®.**
- **If you are using more than one topical eye medication, the medicines should be administered at least 5 minutes apart.**
- **If you have additional questions and concerns, you should contact the office.**

**Check for understanding**

Make sure, when you’re talking to the patients, that you address all of their questions and concerns. Remind them that their eyesight is important and that they need to take care of their eyes, especially after cataract surgery. This way, they will be more likely to follow their post-operative instructions, including how and when to use PROLENSA® properly.

**INDICATION**

- **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.**

**IMPORTANT SAFETY INFORMATION ABOUT PROLENSA®**

- **PROLENSA® contains sodium sulfite, a sulfite that may cause allergic type reactions including anaphylactic type reactions involving anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people.**
- **Sulfite sensitivity is seen more frequently in asthmatics than in nonasthmatics.**
- **All topical nonsteroidal anti-inflammatory drugs (NSAIDs), including bromfenac, may slow or delay healing. Concomitant use of topical NSAIDs and steroids may increase the potential for healing problems.**

- **There is the potential for cross-sensitivity to acetylsalicylic acid, phenylacetic acid derivatives, and other NSAIDs, including bromfenac. Use with caution in patients who have previously exhibited sensitivities to these drugs.**

- **There have been reports that ocularly applied NSAIDs may cause increased bleeding of ocular tissues (including hyphema) in conjunction with ocular surgery.** Use with caution in patients with known bleeding tendencies or who are receiving other medications which may prolong bleeding time.

- **Use of topical NSAIDs may result in keratitis. Patients with evidence of corneal epithelial breakdown should immediately discontinue use of topical NSAIDs, including bromfenac, and should be closely monitored for corneal health.** Patients with complicated ocular surgeries, corneal debridement, corneal epithelial defects, diabetes mellitus, ocular surface disease (eg, dry eye syndrome), rheumatoid arthritis, or repeat cataract 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 patients. Post-marketing experience with topical NSAIDs 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.**

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

- **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 2015.
2. Walters TR, Goldberg JN, Peace JH, Gow JA, for the Bromfenac Ophthalmic Solution 0.07% Once Daily Study Group. Bromfenac ophthalmic solution 0.07%-0.1% is effective for cataract surgery: results of 2 randomized controlled trials. *Ophthalmology.* 2014;121(7):1276-1283.

Please see attached full Prescribing Information.

Mitchell A. Jackson, MD is a board-certified ophthalmologist specializing in cataract and refractive surgery. He received his medical degree from Chicago Medical School, completed his internship at Columbus Hospital and his ophthalmology residency at University of Chicago Hospitals. Currently, Dr. Jackson is the Founder and Medical Director of Jacksoneye in Lake Villa, Illinois, and is also a clinical assistant at the University of Chicago Hospitals. Dr. Jackson is a consultant to Bausch + Lomb, the content of this article is sponsored by Bausch + Lomb.
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. (1)

2 DOSAGE AND ADMINISTRATION

2.1 Recommended Dosing

One drop of PROLENSA ophthalmic solution should be instilled into each 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)

2.2 Use with Other Topical Ophthalmic Medications

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.

5.1 Sulfite Allergic Reactions

Sulfite sensitivity is seen more frequently in certain susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is more frequently seen in asthmatic than in non-asthmatic people.

5.2 Slow or Delayed Healing

Patients undergoing cataract surgery self-administered bromfenac 0.07% or other topical nonsteroidal anti-inflammatory drugs (NSAID) indicated for the treatment of postoperative inflammation and reduction of ocular pain in patients who have undergone cataract surgery.

6 ADVERSE REACTIONS

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

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Treatment of rats at doses of up to 9 mg/kg/day (systemic exposure 90 times the systemic exposure predicted from the recommended human ophthalmic dose (POHD) assuming the human systemic concentration is at the limit of quantification) and rabbits at doses up to 7.5 mg/kg/day (30 times the predicted human systemic exposure) produced no treatment-related malformations in reproduction studies. However, embryofetal lethality and maternal toxicity were observed in rats and rabbits at 9 mg/kg/day and 7.5 mg/kg/day, respectively. In rats, bromfenac treatment caused delayed parturition at 9 mg/kg/day (20 times the predicted human exposure), and caused dystocia, increased neonatal mortality and reduced postnatal growth at 9 mg/kg/day.

9.2 Pediatric Use

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

10.1 Cross-Sensitivity

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

11 DESCRIPTION

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

Bromfenac is a nonsteroidal anti-inflammatory drug (NSAID) that has anti-inflammatory activity. The mechanism of action of PROLENSA is primarily through the inhibition of prostaglandin synthesis by inhibiting cyclooxygenase (COX) enzymes.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Bromfenac 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.

12.3 Pharmacokinetics

The plasma concentration of bromfenac following ocular administration of 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) and is a steady-state in humans.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Bromfenac did not impair fertility when administered to rats at up to 15 mg/kg/day (systemic exposure 200 times the systemic exposure predicted from the recommended human ophthalmic dose (POHD) assuming the human systemic concentration is at the limit of quantification) and 5 mg/kg/day (30 times the predicted human systemic exposure), respectively, revealed no significant increases in tumor incidence.

Bromfenac did not show mutagenic potential in various in vitro genotoxicity studies, including the reverse mutation, chromosomal aberration, and micronucleus tests. Bromfenac did not impair fertility when administered to rats at doses up to 0.5 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% (POHD) for the treatment of postoperative inflammation and reduction of ocular pain was evaluated in a double-blind, randomized, parallel-group placebo-controlled study. Patients undergoing cataract surgery self-administered bromfenac 0.07% or placebo 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 (cell and mucus) was achieved on Day 5. The intent-to-treat analysis from all assessments, complete clearance of ocular inflammation (cell and mucus) was achieved on Day 5. The intent-to-treat analysis from all assessments, complete clearance of ocular inflammation (cell and mucus) was achieved on Day 5. The intent-to-treat analysis from all assessments, complete clearance of ocular inflammation (cell and mucus) was achieved on Day 5. The intent-to-treat analysis from all assessments, complete clearance of ocular inflammation (cell and mucus) was achieved on Day 5. The intent-to-treat analysis from all assessments, complete clearance of ocular inflammation (cell and mucus) was achieved on Day 5. The intent-to-treat analysis from all assessments, complete clearance of ocular inflammation (cell and mucus) was achieved on Day 5.