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.

IMPORTANT SAFETY INFORMATION ABOUT PROLENSA®
- PROLENSA® 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 nonasthmatic people.

Please see additional Important Safety Information throughout.

Participants of the roundtable discussion are paid consultants of Bausch + Lomb.
GOALS OF THE ROUNDTABLE

- Identify best practices for appropriate ophthalmic NSAID use
- Review the various clinical and commercial factors that influence ophthalmic NSAID selection & utilization

By defining pull-through protocols for ophthalmic NSAIDs and identifying best practices to ensure that patients receive their treatments as prescribed, cataract surgeons can help ensure successful post-cataract surgery outcomes. When it comes to PROLENSA® there are important characteristics to consider which drive prescribing habits. — William Trattler, MD

OPHTHALMIC NSAIDs—WHY THEY MATTER

WILLIAM TRATTLER, MD: You’re all familiar with the cascade of events associated with anterior segment inflammation after cataract surgery. Inflammation begins at the time we start our surgical procedure and continues afterwards, and NSAIDs play a key role in helping us manage this inflammation.1 It may be hard to believe, but there was a time when cataract surgeons didn’t use ophthalmic NSAIDs to manage postoperative inflammation and pain. Do you recall that time?

CYNTHIA MATOSSIAN, MD: I remember that time clearly. The arrival of ophthalmic NSAIDs was an important therapeutic advance.

WILLIAM TRATTLER, MD: Adoption of ophthalmic NSAIDs was not instantaneous. Although it took a long time for cataract surgeons to adopt NSAIDs as a part of their post-cataract surgery treatment protocol, now it feels like the clear majority of cataract surgeons use NSAIDs.

PARAG MAJMUDAR, MD: There was a brief period when it was believed that NSAIDs were associated with many complications. However, as more ophthalmic NSAIDs, including PROLENSA®, entered the market, we saw clinical utility in their use and became more comfortable with their use. My understanding is that cataract surgeons typically use both ophthalmic NSAIDs and corticosteroids to manage postoperative inflammation.1

CYNTHIA MATOSSIAN, MD: NSAIDs are an essential part of my armamentarium after cataract surgery. Utilization of an NSAID helps ensure good surgical outcomes for my patients.

RAJESH RAJPAL, MD: We have an obligation to prescribe NSAID eye drops to our patients when such drops are needed.

“\The arrival of ophthalmic NSAIDs was an important therapeutic advance.\” — CYNTHIA MATOSSIAN, MD

WHAT’S THE PROTOCOL? MANAGING TREATMENT PULL-THROUGH

KARL STONECIPHER, MD: Post-cataract surgery outcomes have become progressively better over time—in fact, cataract surgery is now viewed to be as routine as LASIK. I believe that is partly due to appropriate perioperative NSAID use and consistent pull-through of NSAID treatment protocols.

WILLIAM TRATTLER, MD: What do you do if you think appropriate NSAID treatment protocols are not being followed?

RAJESH RAJPAL, MD: Sometimes, I will have a patient who calls my office the day before cataract surgery and...

IMPORTANT SAFETY INFORMATION ABOUT PROLENSA® (CONT.)

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

Please see additional Important Safety Information throughout.
states that they didn’t take their NSAID eye drops. They
ask me, “How important is it, doctor? You told me to use
these drops on the day before surgery, but I didn’t. Should
we cancel the surgery?” In my practice, I don’t cancel the
surgery, but, rather, I ensure that the patient receives their
eye drops on the day of surgery and then continues the
medication postoperatively.

CYNTHIA MATOSSIAN, MD: I take additional precautions in
these types of patients, because they have volunteered that
they have not been compliant. This is a major red flag for
me. For these patients, I am doubly careful to ensure that
they take their prescribed ophthalmic drops.

PARAG MAJMUDAR, MD: With that in mind, do you think
it is appropriate to query the patient, instead of waiting for
them to volunteer that information?

CYNTHIA MATOSSIAN, MD: I don’t personally query them,
but the nurses do. This is an important part of our protocol.
The nurses will ask the patient, “Have you been using your
drops?” If the answer is no, the nurses will know to enforce
treatment protocol more strictly.

KARL STONECIPHER, MD: In my experience, it’s very
rare for a patient to volunteer that they did not take their
drops. Therefore, I believe that it is better to have a single,
consistent protocol that I apply to all patients. This includes
proper preoperative preparation, as well as use of an
appropriate postoperative anti-inflammatory medication.

CYNTHIA MATOSSIAN, MD: One of the ways I enforce
treatment protocols is by discussing the possibility of
pain after cataract surgery. Patients often fear pain. As
surgeons, we do everything we can to help alleviate
patients’ fear of pain. If I tell them, “This medicine will help
with the pain,” then the patient has buy-in to help make the
post-cataract surgery process as painless as possible.

PARAG MAJMUDAR, MD: I think that having a protocol
that we use on all patients is a good strategy. Proper
preparation and using the prescribed medication are very
important because it is difficult to know which patients are
using their medication and in what regimen.

WILLIAM TRATTLER, MD: Educating the staff is critical.
It’s important that my staff knows how to check refraction,
check visual acuity, and assess patient history. One of
the most important parts of being a physician is having
a well-trained staff to help handle our patients.

CYNTHIA MATOSSIAN, MD: The key is to have all
stakeholders on the same page. Education starts with the
physician and filters down to the surgical coordinators,
technicians, and even the front desk receptionists.
Educating the team takes time and effort, but it is a core
physician responsibility.

PARAG MAJMUDAR, MD: Patient comfort is closely
tied to NSAID treatment protocol adherence. It’s our
responsibility as surgeons for our practices to enforce
NSAID pull-through. I meet with my patients, review the
NSAID administration instructions, and explain how the
NSAID is used at the correct dosing frequency. During
follow-up examinations, I assess for the presence of any
side effects.

KARL STONECIPHER, MD: Messaging also must be
consistent throughout the practice. What the physician says
must be the same as what the front office staff says, which
must be the same as what the technicians and patient
care coordinators say. This helps enforce consistent NSAID
pull-through. This constant repetition helps the patient
understand the cataract surgery procedure and the NSAID
use instructions.

RAJESH RAJPAL, MD: Ultimately, a good treatment
protocol boils down to having a well-trained staff that
knows how to manage the patient before and during
the post-cataract surgery recovery process. I have
multiple touch points with all my patients—this helps
decrease the number of phone calls and improve
compliance in my practice. I also use surgical counselors,
who sit down with patients and explain appropriate NSAID
use protocols, with the goal of explaining why we prescribe
this specific medication.

PARAG MAJMUDAR, MD: Patient comfort is closely
tied to NSAID treatment protocol adherence. It’s our
responsibility as surgeons for our practices to enforce
NSAID pull-through. I meet with my patients, review the
NSAID administration instructions, and explain how the
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follow-up examinations, I assess for the presence of any
side effects.

PROLENSA® DELIVERS A CONSISTENT
DOSE WITH NO SHAKING REQUIRED

DOSAGE: 1 drop 1 day prior to surgery, continued
on the day of surgery, and through the first 14 days
post-surgery.
RAJESH RAJPAL, MD: My priority is ensuring that the entire post-cataract surgery experience is as favorable as possible. This includes ensuring that my patient uses their medication without difficulties and instills their drops as prescribed. These are all elements of my treatment protocol.

IMPORTANT FACTORS TO CONSIDER WHEN SELECTING AN APPROPRIATE OPHTHALMIC NSAID

WILLIAM TRATTLER, MD: This conversation brings up a relevant topic—the debate around the relative merits and drawbacks of various types of eye drops.

RAJESH RAJPAL, MD: I prefer to prescribe branded drops. I prefer to use a branded bromfenac-containing drop such as PROLENSA®. I’m partial to PROLENSA® because halogenation with bromine has been demonstrated to increase corneal penetration.1 However, if my patients can’t procure my recommended eye drops for some reason, or if they want to use a generic drop, I am willing to discuss that with them. Regardless, it is important to me to ensure that my patients have an appropriate ophthalmic drop for their needs.

WILLIAM TRATTLER, MD: Many generic options are available—bromfenac, diclofenac, flurbiprofen, ketorolac, and nepafenac. What are your experiences with these products?

CYNTHIA MATOSSIAN, MD: With the availability of generic medications, including ophthalmic NSAIDs, available for patients at the pharmacy, I believe that it is important to educate patients on why I prescribe a branded ophthalmic NSAID when a generic equivalent is not available.

RAJESH RAJPAL, MD: Patients may be confused about the dosing instructions for their ophthalmic NSAID, regardless of whether it is a branded or generic NSAID. I don’t want any patient to use an NSAID inappropriately—for example, using an NSAID four times per day when it is intended to be used once or twice per day. For this reason, I take extra steps to educate my patients on how to properly dose and administer their NSAIDs, and my practice always tries to review a patient’s status in advance of cataract surgery. Our surgical counselors are aware of which products the patient is using, how to best prepare the patient for surgery, and how to coach the patient on proper postoperative drop use.

PARAG MAJMUDAR, MD: We’ve made tremendous advances in cataract surgery in terms of technology and giving patients an optimal clinical outcome. If I have a patient paying thousands of dollars out of pocket for a premium intraocular lens (IOL) implant, I think it’s appropriate to give that patient a branded NSAID when a generic equivalent is not available. I think our office staffs need to be educated on the risk-benefit profiles of NSAIDs, regardless of whether a branded or generic NSAID is prescribed. Our office staffs also need to be educated on the importance of not switching to a formulation different from the one prescribed.

CYNTHIA MATOSSIAN, MD: I believe that a key factor in creating a positive patient journey is minimizing the dosing burden. If my patient is receiving an advanced-technology IOL implant, I prefer that they use an NSAID with once per day dosing. I also like an ophthalmic NSAID that provides dose uniformity without the need to shake the bottle. These are all elements of the white-glove experience that my cataract surgery patients expect.

IMPORTANT SAFETY INFORMATION ABOUT PROLENSA® (CONT.)

• 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.

Please see additional Important Safety Information throughout.
WILLIAM TRATTLER, MD: A number of biochemical factors can also drive NSAID selection, as these can influence drug penetration, efficacy, and safety. I’ve observed that drug development has focused on increasing the effective dose, evolving the molecular design, and enhancing lipophilicity and solubility. Clinical development has focused on improving efficacy and tolerability profiles. The confluence of these factors has made modern NSAIDs an integral part of the treatment paradigm.

PARAG MAJMUDAR, MD: Considerable effort has gone into the development of ophthalmic NSAID formulations. As physicians, we must help educate patients, pharmacies, and insurance companies on formulation attributes as well as clinical efficacy and safety outcomes.

WILLIAM TRATTLER, MD: It’s important to recognize that pharmacies may take the choice of NSAID out of the physician’s hands. Cost-conscious patients may request less expensive NSAID options. This is why patient education about the NSAIDs we prescribe is so important.

KARL STONECIPHER, MD: I’ve had instances where I recommend that my patients visit a local pharmacy that my practice has already communicated my post-treatment preferences. At such pharmacies, I know that the prescription will be filled as written.

RAJESH RAJPAL, MD: In this regard, coupons have been assets to my post-cataract surgery patients. Coupons are a good complement to NSAID education for cost-conscious patients. A patient needs to be educated in advance of going to the pharmacy in order to ensure that their ophthalmic NSAID prescription isn’t switched against their wishes. The patient should be empowered to ensure that their NSAID is dispensed as written.

WILLIAM TRATTLER, MD: I do have the occasional patients who truly cannot afford branded NSAIDs. I provide samples of branded NSAIDs when I encounter these patients. I also inform these patients that Bausch + Lomb offers co-pay coupons as well as patient assistant programs, if they are eligible.

As physicians, we must help educate patients, pharmacies, and insurance companies on formulation attributes as well as clinical efficacy and safety outcomes. — PARAG MAJMUDAR, MD

WHY WE CHOOSE PROLENSA®, AN OPHTHALMIC NSAID HALOGENATED WITH BROMINE

WILLIAM TRATTLER, MD: Everyone here recognizes that the dosing frequency of anti-inflammatory eye drops is an important consideration after cataract surgery. Notably, PROLENSA® only needs to be administered once per day during the perioperative and postoperative periods. One drop of PROLENSA® 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.

CYNTHIA MATOSSIAN, MD: An important feature of an ophthalmic formulation is its pH, which can affect corneal penetration. The pH of PROLENSA® is 7.8—a slightly basic pH that may enhance corneal penetration. By comparison, the pH of Bausch + Lomb’s previous bromfenac formulation is 8.3. The pH of Bausch + Lomb’s bromfenac formulation has evolved over time as part of Bausch + Lomb’s long-term formulation optimization efforts.

RAJESH RAJPAL, MD: I would also add that bromfenac is a bioactive compound and not a prodrug. This is important because I cannot always anticipate the status of the patient’s ocular surface and when the conversion from prodrug to active drug will occur. I find myself asking, “Will the appropriate enzymes that regulate the absorption, metabolism, and pharmacokinetics of a prodrug NSAID be present on the ocular surface?” With PROLENSA®, I don’t have this concern.

WILLIAM TRATTLER, MD: Let’s consider the clinical trial data. Many of us have been involved in clinical trials for ophthalmic NSAIDs, and we have strong perspectives...
on the meaning of these outcomes. The data from the 2 PROLENSA® phase 3 clinical trials were pooled, and it was found that the proportion of subjects who achieved complete clearance of ocular inflammation (summed ocular inflammation score [SOIS] of 0) by Day 15, was significantly higher in the PROLENSA® group than in the vehicle group (Figure 1). It’s impressive that nearly half of patients receiving PROLENSA® had an SOIS of 0 at Day 15. I can usually find a sporadic inflammatory cell when examining a patient—it’s not especially challenging. For this reason, I find the PROLENSA® clinical data to be powerful.

KARL STONECIPHER, MD: Another important observation is that a significantly greater proportion of subjects were pain free in the PROLENSA® group than in the vehicle group at Day 1 (Figure 2), and this continued through the remaining follow-up visits. To me, the proportion of pain-free patients in the PROLENSA® group is clinically important.

WILLIAM TRATTLER, MD: What is your perception of the adverse event profile of PROLENSA®?

CYNTHIA MATOSSIAN, MD: The clinical trial data show that the overall incidence of adverse events affecting the study eye was significantly lower in the PROLENSA® group than in the placebo group (Figure 3). The incidences of specific ocular adverse events appear low and similar when comparing PROLENSA® and vehicle. The most commonly reported adverse reactions in 3% to 8% of patients were anterior chamber inflammation, foreign body sensation, eye pain, photophobia, and blurred vision.

PARAG MAJMUDAR, MD: Adverse events are always a concern, but I pay more attention to adverse events that consistently occur either more or less frequently when a specific product is used.

WILLIAM TRATTLER, MD: Based on these perspectives, how would you summarize your overall impression of PROLENSA®?

RAJESH RAJPAL, MD: PROLENSA® is effective for post-cataract surgery use because it decreases ocular inflammation and has an acceptable tolerability profile, while meeting my patients’ ocular comfort needs.

PARAG MAJMUDAR, MD: I feel confident in PROLENSA® because the bromfenac molecule has been in ophthalmic use for a long time, and because PROLENSA® has a track record of a demonstrated efficacy and tolerability profile. I take the time to educate my patients about this.

CYNTHIA MATOSSIAN, MD: To me, PROLENSA® is a potent ophthalmic formulation that penetrates well and helps control inflammation and pain following cataract surgery.
IMPORTANT SAFETY INFORMATION ABOUT PROLENSA® (CONT.)

• There have been reports that ocularly applied NSAIDs may cause increased bleeding of ocular tissues (including hyphemas) 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 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 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.

Please see additional Important Safety Information throughout. Please see full Prescribing Information on page 8.


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