Discussing the cost of PROLENSA® with your patients

Talking to your patients ahead of time about the cost of treatment is important. You may be able to minimize the calls you and your medical practice will receive from the pharmacy. In addition, you may be able to help reduce treatment costs for your patients.

Why PROLENSA®?
I have chosen PROLENSA® because the clinical profile of PROLENSA® is appropriate for you. I have confidence in its proven efficacy, safety, and once-daily dosing.

Is there a generic equivalent for PROLENSA®?
• PROLENSA® is a nonsteroidal anti-inflammatory drug (NSAID). PROLENSA® is manufactured by Bausch + Lomb, and there is no generic equivalent available.

How much can you expect to pay for PROLENSA® at the pharmacy?
• If you are eligible, I can offer you a valuable Copay Card that can reduce your out-of-pocket costs for PROLENSA®.
• You may pay as little as $30 or up to $200 if you use a PROLENSA® Copay Card for your prescription, depending on your insurance.
• I understand that this drug may come with a significant out-of-pocket expense, and I have factored this into my decision to prescribe PROLENSA® for you. I encourage you to have the pharmacist fill the prescription as written.
• Your pharmacist may encourage you to use a generic medication instead of the brand I have prescribed. I am aware of the various treatment alternatives available for you and have prescribed PROLENSA®, a treatment that has no generic equivalent.

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
• The most commonly reported adverse reactions in 3%-8% of patients were anterior chamber inflammation, foreign body sensation, eye pain, photophobia, and blurred vision.
• 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 on next page, and be sure to review information on next with your patients.
What are the product features?

I have specifically chosen PROLENSA® for you for several important reasons:

• At Day 1, approximately 4 of 5 patients who used PROLENSA® were pain free\(^1,2\)
  — Individual results may vary
• PROLENSA® rapidly reduced inflammation versus placebo after cataract surgery\(^2\)
  — Significant results were seen at Day 8 and Day 15
  — Individual results may vary
• You only have to use PROLENSA® once per day, and use is short term.\(^1\) There are no ongoing monthly costs
  — One drop is administered into the affected eye beginning 1 day prior to surgery, continued on the
day of surgery, and through the first 14 days post surgery\(^1\)
• Because PROLENSA® is a solution, you don’t have to shake it before use\(^1,3\)
• Investment in your postoperative cataract care is important
• The most common side effects (seen in 3%-8% of patients) were inflammation of the front of the eye,
  foreign body sensation, eye pain, light sensitivity, and blurred vision.

What else do my patients need to know about PROLENSA®?

• Counsel patients about additional factors associated with PROLENSA®, including slowed or delayed
  healing, the sterility of the dropper tip, concomitant use of contact lenses, and concomitant use of
  topical ocular therapy\(^1\)
• You should also advise patients about any additional considerations you may deem medically necessary

IMPORTANT SAFETY INFORMATION (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.
• 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 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.
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) DOSE 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) DOSE FORMS AND STRENGTHS

Topical ocular solution: bromfenac 0.07% (3)

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TO REPORT SUSPECTED ADVERSE REACTIONS, contact Bausch & Lomb Incorporated at 1-800-323-0000, or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Full prescribing information are not listed.

5.5 Keratitis and Corneal Reactions

One drop of topical NSAID solution should be applied to the affected eye once daily beginning 1 day prior to surgery, continued on the day of surgery, and through the first 14 days of the postoperative period. (2.1)

2.2 Use with Other Topical Ophthalmic Medications

PROLENSA ophthalmic solution may be administered in conjunction with other topical ocular 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 ocular solution: bromfenac 0.07% (3)

CONTRAINDICATIONS

None (4)

WARNINGS AND PRECAUTIONS

- Topical 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

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 of severity of corneal adverse events. (5.5)

6.5 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. (6.5)

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 Incorporated at 1-800-323-0000, or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. See 17 for PATIENT COUNSELING INFORMATION

Revised: 4/2013
Bromfenac sodium is yellow to orange crystalline powder. The molecular weight of bromfenac sodium is 383.17. Bromfenac sodium is designated chemically as sodium [2-amino-3-(4-bromobenzoyl) phenyl] acetate sesquihydrate, (NSAID) for ophthalmic use. Each mL of PROLENSA ophthalmic solution is approximately 300 mOsmol/kg.

11 DESCRIPTION
PROLENSA (bromfenac ophthalmic solution) 0.07% is a sterile, topical, nonpreserved, ophthalmic solution (NSAID) for use in the treatment of ocular inflammation by day 15. In the intent-to-treat analysis of subjects who had complete clearance of ocular inflammation by day 15. The primary efficacy endpoint was the proportion of subjects who had complete clearance of ocular inflammation by day 15. The chemical structure for bromfenac sodium sesquihydrate is:

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\text{C}_{15}\text{H}_{11}\text{BrNNaO}_3\cdot 1\frac{1}{2}\text{H}_2\text{O}
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The molecular weight of bromfenac sodium is 383.17. Bromfenac sodium is yellow to orange crystalline powder. The molecular weight of bromfenac sodium is 383.17. Bromfenac sodium is designated chemically as sodium [2-amino-3-(4-bromobenzoyl) phenyl] acetate sesquihydrate, (NSAID) for ophthalmic use. Each mL of PROLENSA ophthalmic solution is approximately 300 mOsmol/kg. PROLENSA (bromfenac ophthalmic solution) 0.07% is supplied in a white LDPE plastic squeeze bottle with a 15 mm flip-top applicator. The chemical structure for bromfenac sodium sesquihydrate is:

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