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.

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.

DOSE FORMS AND STRENGTHS

Topical ophthalmic solution: bromfenac 0.07% (3)

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-1085 or www.fda.gov/medwatch.
See 17 FOR PATIENT COUNSELING INFORMATION.

Revised: 6/2016

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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 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% (3)

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 NSAIDs 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 sensitivity 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 ocularily applied NSAIDs may cause increased bleeding of ocular tissues (including hyphemas) in conjunction with surgical procedures. 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. In post-marketing experience with topical NSAIDs, keratitis or ocular surface disease (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 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 topical NSAIDs may result in epithelial breakdown and corneal thinning, 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 topical NSAIDs may result in epithelial breakdown and corneal thinning, 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.

5.6 Contact Lens Wear

Contact lenses may be reinserted after 10 minutes following administration of PROLENSA. The preservative in PROLENSA, benzalkonium chloride, may be absorbed by soft contact lenses. Lenses may be remeasured 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.

ADVERSE REACTIONS

None

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)

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-1085 or www.fda.gov/medwatch. See 17 FOR PATIENT COUNSELING INFORMATION.
Bromfenac did not show mutagenic potential in various mutagenicity studies, including the reverse mutation, chromosomal aberration, and microsomeless 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 PHARMACOLOGY

14.1 Ocular Inflammation and Pain

Bromfenac 0.07% OD for the treatment of postoperative inflammation and reduction of ocular pain was evaluated in two multi-center, double-masked, parallel-group, placebo-controlled studies. Patients undergoing cataract surgery self-administered bromfenac 0.07% or vehicle once daily, beginning the day of surgery, continuing the morning of surgery and for 14 days after surgery. Complete clearance of ocular inflammation (0 cell and no flare) was observed on Day 13 and 14 post surgery using light biomicroscopy. 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.

<table>
<thead>
<tr>
<th>Study</th>
<th>Visit</th>
<th>Bromfenac 0.07%</th>
<th>Vehicle</th>
<th>Difference (%)</th>
<th>Study (Asymptotic 95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Study</td>
</tr>
<tr>
<td>Study</td>
<td>1</td>
<td>At 27/112</td>
<td>17.6 (8.4, 26.8)</td>
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<tr>
<td></td>
<td></td>
<td>At 15</td>
<td>32.5 (21.4, 43.8)</td>
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<tr>
<td>Study</td>
<td>2</td>
<td>At 33/110</td>
<td>17.3 (6.7, 27.9)</td>
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<tr>
<td></td>
<td></td>
<td>At 8</td>
<td>51/110 (27.3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>At 15</td>
<td>20.5 (8.7, 31.3)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

16 HOW SUPPLIED/DISTRIBUTION AND HANDLING

PROLENSA (bromfenac ophthalmic solution) 0.07% is supplied in a white LDPE dispenser caddy 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)


17 PATIENT COUNSELING INFORMATION

SLODED OR DELAYED HEALING

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

Sterility of Dropper Tip

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

Concomitant Use of Contact Lenses

Advises patients to remove contact lenses prior to instillation of PROLENSA. The therapeutic use of PROLENSA, benzalkonium chloride, may be absorbed by soft contact lenses. Lenses may be reinserted after 10 minutes following the instillation of PROLENSA.

Concomitant 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 International, Inc., Bridgewater, NJ 08807 USA

Under license from

Senju Pharmaceutical Co., Ltd.

Osaka, Japan 541-0046

Bausch & Lomb Incorporated

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