There have been reports that potential for increased bleeding time due to interference with some NSAIDs, including bromfenac, there exists the sensitivities to these drugs. Therefore, caution should be used when treating individuals who have previously exhibited sensitivities to these drugs.

There is the potential for cross-sensitivity to acetylsalicylic acid, corticosteroids are also known to slow or delay healing. Post-marketing experience with topical NSAIDs also suggests that patients with complicated ocular surgeries, corneal denervation, corneal epithelial defects, diabetes mellitus, ocular surface diseases (e.g., dry eye syndromes), 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. Posterior NSAs should be used with caution in these patients. Post-marketing experience with topical NSAs 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 corneal adverse events.

5.5 Keratitis and Corneal Reactions

One drop of topical NSAs may result in keratitis. In some susceptible patients, continued use of topical NSAs 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 NSAs, including bromfenac, and should be referred to an ophthalmologist. Post-marketing experience with topical NSAs suggests that patients with complicated ocular surgeries, corneal denervation, corneal epithelial defects, diabetes mellitus, ocular surface diseases (e.g., dry eye syndromes), 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 NSAs should be used with caution in these patients.

8.4 Pediatric Use

8.5 General Use

11 DESCRIPTION

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

12.2 Pharmacokinetics

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

14 CLINICAL STUDIES

14.1 Ocular Inflammation and Pain

16 HOW SUPPLIED/STORAGE AND HANDLING

17 PATIENT COUNSELING INFORMATION

17.1 Contact Lens Use

17.2 Sterility of Dropper Tip

17.3 Concomitant Use of Contact Lenses

17.4 Concomitant Topical Ocular Therapy

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

FULL PRESCRIBING INFORMATION: CONTENTS

1 INDICATIONS AND USAGE

2 DOSAGE AND ADMINISTRATION

2.1 Recommended Dosing

2.2 Use with Other Topical Ophthalmic Medications

3 DOSAGE FORMS AND STRENGTHS

4 CONTRAINDICATIONS

5 WARNINGS AND PRECAUTIONS

5.1 Sulfite Allergic Reactions

5.2 Contact Lens Wear

5.3 Potential for Cross-Sensitivity

5.4 Increased Bleeding Time

5.5 Keratitis and Corneal Reactions

5.6 Adverse Reactions

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

8.2 Nursing Mothers

14 CLINICAL STUDIES

14.1 Ocular Inflammation and Pain

16 HOW SUPPLIED/STORAGE AND HANDLING

17 PATIENT COUNSELING INFORMATION

17.1 Contact Lens Use

17.2 Sterility of Dropper Tip

17.3 Concomitant Use of Contact Lenses

17.4 Concomitant Topical Ocular Therapy

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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 0.005 mg of bromfenac sodium sesquihydrate (equivalent to 0.004 mg of bromfenac free acid). The USAN name for bromfenac sodium sesquihydrate is bromfenac. Bromfenac sodium is designated chemically as sodium 3-(4-bromophenyl)phenylpropionic acid (C₁₇H₁₇BrNO₂).The chemical structure for bromfenac sodium sesquihydrate is shown in the following table.