Bromday™ (bromfenac ophthalmic solution) 0.09%

FULL PRESCRIBING INFORMATION

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use Bromday (bromfenac ophthalmic solution) 0.09% safely and effectively. See full prescribing information for Bromday. Bromday (bromfenac ophthalmic solution) 0.09% Initial U.S. Approval: 1997

INDICATIONS AND USAGE

Bromday 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 extraction (1).

DOSE AND ADMINISTRATION

Instil one drop into the affected eye(s) 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 ophthalmic solution: bromfenac 0.09% (3)

FULL PRESCRIBING INFORMATION

CONTENTS:

1. INDICATIONS AND USAGE

Bromday (bromfenac ophthalmic solution) 0.09% is indicated for the treatment of postoperative inflammation and reduction of ocular pain in patients who have undergone cataract surgery. (2.1)

2. DOSAGE AND ADMINISTRATION

2.1 Recommended Dosing

For the treatment of postoperative inflammation in patients who have undergone cataract extraction, one drop of Bromday ophthalmic solution should be applied to the affected eye(s) 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. (2.1)

2.2 Use with Other Topical Ophthalmic Medications

Bromday ophthalmic solution may be administered in conjunction with other topical ophthalmic medications such as alpha-agonists, beta-blockers, carboxy anhydrase inhibitors, cycloptics, and mydriatics. Drops should be administered at least 5 minutes apart. (2.2)

3. DOSAGE FORMS AND STRENGTHS

Topical ophthalmic solution: bromfenac 0.09% (3)

4. CONTRAINDICATIONS

None. (4)

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 adverse episodes in certain susceptible individuals. 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. (5.1)

5.2 Slow or Delayed Healing

All topical nonsteroidal anti-inflammatory drugs (NSAIDs) may slow or delay healing. Topical corticosteroids are also known to slow healing. Concomitant use of topical NSAIDs and topical steroids may increase the potential for healing problems. (5.2)

5.3 Potential for Cross-Sensitivity

There is the potential for cross-sensitivity to acetylsalicylic acid, phenylacetic acid derivatives, and other NSAIDs. Therefore, caution should be used when treating individuals who have previously exhibited sensitivities to these drugs. (5.3)

5.4 Increased Bleeding Time

With some NSAIDs, there exists the potential for increased bleeding time due to interference with platelet aggregation. There have been reports that ocularty applied NSAIDs may cause increased bleeding of ocularty tissues (including hypHEMA) in conjunction with conjunctival surgery. (5.4)

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, 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 NSAIDs and should be closely monitored for corneal health. (5.5)

5.6 Contact Lens Wear

Bromday should not be administered while wearing contact lenses. (5.6)

6. ADVERSE REACTIONS

6.1 Clinical Trial Experience

The most commonly reported adverse reactions reported following use of bromfenac after cataract surgery include: abnormal sensation in eye, conjunctival hyperemia, eye irritation (including burning/stinging), eye pain, eye pruritus, eye redness, headache, and iti. These events were reported in 2-7% of patients. (6.1)

6.2 Post-Marketing Experience

The following adverse reactions have been identified during post-marketing use of bromfenac ophthalmic solution 0.09% in clinical practice. Because they are reported voluntarily from a population of uncontrolled subjects, frequency cannot be made. The events, which have been chosen for inclusion due to either their seriousness, frequency of reporting, possible causal connection to topical bromfenac ophthalmic solution 0.09% or a combination of these factors, may not reflect the frequency of occurrence in practice, nor are they necessarily causal in their occurrence during pregnancy only if the potential benefit justifies the potential risk to the fetus. Nonteratogenic Effects: Because of the known effects of prostaglandin biosynthesis-inhibiting drugs on the fetal cardiovascular system (closure of ductus arteriosus), the use of Bromday ophthalmic solution during late pregnancy should be avoided. (6.2)

8.3 Nursing Mothers

Caution should be exercised when Bromday is administered to a nursing woman. (8.3)

8.4 Pediatric Use

Caution should be exercised when Bromday is administered to pediatric patients aged 18 years and older. (8.4)

11. DESCRIPTION

Bromday contains 1.035 mg bromfenac sodium (equivalent to 0.951 mg bromfenac free acid) per mL of ophthalmic solution. Each mL of Bromday ophthalmic solution contains: (11.1)

Bromfenac sodium, benzalkonium chloride (0.05 mg/mL) Preservative: benzalkonium chloride (0.05 mg/mL)

12. CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Bromfenac is a nonsteroidal anti-inflammatory drug (NSAID) that has anti-inflammatory activity. The mechanism of its action is thought to be due to its ability to block prostaglandin synthesis by inhibiting cyclooxygenase-1 and 2. Prostaglandins have been shown in many animal models to be mediators of certain kinds of intracocular inflammation. In studies performed in animal eyes, prostaglandins have been shown to produce disruption of the blood-aqueous humor barrier, vasodilation, increased vascular permeability, leukocytosis, and increased intraocular pressure. 12.3 Pharmacokinetics

The plasma concentration of bromfenac following ocularty administration of 0.09% Bromday (bromfenac ophthalmic solution) in humans is unknown. Based on the maximum proposed dose of one drop to the eye (0.045 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) at steady-state in humans. 13. NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis and Impairment of Fertility

Long-term carcinogenicity studies in rats and mice given oral doses of bromfenac up to 0.6 mg/kg/day (900 times the recommended human ophthalmic dose [RHOD]) of 1.67 mcg/kg in 60 kg person on a mg/kg/day basis (assumed absorbed) and 5 mg/kg/day (7500 times RHOD), respectively revealed no significant increases in tumor incidence. Bromfenac did not show mutagenic potential in various mutagenicity studies, including the reverse mutation, chromosomal aberration, and micronucleus 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 (1300 and 300 times RHOD, respectively).

14. CLINICAL STUDIES

14.1 Ocular inflammation and pain following cataract surgery

Clinical efficacy was evaluated in three randomized, double-masked, placebo-controlled trials in which subjects requiring cataract surgery were assigned to Bromday or placebo. Patients were dosed with one drop per eye starting the day before surgery and continuing for 14 days. The primary endpoint was decreasing intraocular inflammation by day 15. An additional efficacy endpoint was the number of patients who were pain free on day 1 after cataract surgery. In 2 of the 3 studies, Bromday ophthalmic solution had statistically significant higher incidence of completely clearing inflammation (46-47% vs. 25-29%) and also had a statistically significant higher incidence of subjects that were pain free at day 1 post-cataract surgery. (14.1)

16. HOW SUPPLIED/STORAGE AND HANDLING

Bromday (bromfenac ophthalmic solution) 0.09% is supplied in a white LDPE plastic squeeze bottle with a 15 mm LDPE white dropper-tip and 15 mm polypropylene gray cap as follows: 1.7 mL in 7.5 mL container (NDC 67425-999-17) STORAGE Store at 15° to 25°C (59° to 77°F). (16.6)

17. PATIENT COUNSELING INFORMATION

17.1 Slowed or Delayed Healing

Patients should be advised of the possibility that slow or delayed healing may occur while using NSAIDs. (17.1)

17.2 Sterility of Dropper Tip

Patients should be advised not to touch dropper tip to any surface, as this may contaminate the product. (17.2)

17.3 Concomitant Use of Contact Lenses

Contact lenses should not be worn during the use of this product. (17.3)

17.4 Concomitant Topical Ocular Medication

If more than one topical ocular medication is being used, the medicines should be administered at least 5 minutes apart Rx

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