

New Drug Bulletin:

Bromfenac ophthalmic solution 0.09% (Xibrom™ - ISTA Pharmaceuticals)

February 20, 2007

Written by Matthew Call, PharmD Student

Edited by Shannon Howarth, PharmD, Drug Information Specialist

Bromfenac ophthalmic solution 0.09% is a sterile nonsteroidal anti-inflammatory agent (NSAID) and is labeled for use in treatment of ocular inflammation and pain secondary to cataract extraction surgery. FDA approval of labelling for inflammation was granted in May 2004 and labelling for pain in July 2005. Diclofenac sodium ophthalmic solution 0.1% has similar labelling. Bromfenac blocks the synthesis of prostaglandins through the cyclooxygenase (COX) 1 and 2 enzymes. Prostaglandins mediate ocular inflammation.

At recommended dosing, plasma concentrations are below the limits of quantification; therefore, pharmacokinetic parameters are undefined.

There are currently no published trials comparing bromfenac ophthalmic solution with other topical NSAIDs. Approval was based on two randomized, double-masked, placebo-controlled clinical trials. Patients with an ocular inflammation score greater than or equal to 3 following cataract surgery were randomized 2:1 to bromfenac ophthalmic solution or vehicle. Patients instilled one drop twice daily for 14 days starting the day after surgery. Bromfenac ophthalmic solution reduced ocular inflammation to trace inflammation or clearing in 62-66% of patients compared with placebo which reduced inflammation in 40-48% of patients. In patients reporting pain after surgery, mean time to pain resolution in the bromfenac group was 2 days versus 4 days for placebo.

Adverse events included the following: abnormal sensation in eye, conjunctival hyperemia, eye irritation (including burning/stinging), eye pain, eye redness, headache, and iritis. These events were reported in clinical trials at rates of 2-7%. Post-marketing voluntary reporting has identified the following adverse events: corneal erosion, corneal perforation, corneal thinning, and epithelial breakdown. Bromfenac ophthalmic solution contains sodium sulfite, which can cause serious allergic reactions in susceptible people. No significant drug interactions are reported.

Instill one drop in the affected eye(s) twice daily beginning 24 hours after cataract surgery and continuing for no more than two weeks. Longer use is associated with a higher risk for corneal erosion and other corneal events.

Bromfenac ophthalmic solution is available as a sterile aqueous solution containing 0.09% bromfenac by weight. It has a pH of 8.3 and an osmolality of approximately 300 mOsmol/kg. It contains benzalkonium chloride, boric acid, sodium sulfite anhydrous, disodium edetate, polysorbate, povidone, sodium borate and purified water USP as inactive ingredients. It is supplied in 2.5 mL and 5 mL aliquots. The following table shows a comparison of average wholesale price (AWP) and wholesale acquisition cost (WAC) for topical ophthalmic bromfenac and diclofenac.

Cost of Select Ophthalmic NSAIDs

Agent	Aliquot	AWP	WAC
Xibrom™ bromfenac ophthalmic solution	2.5 mL	\$80.00	\$64.00
Xibrom™ bromfenac ophthalmic solution	5 mL	\$156.25	\$125.00
Voltaren® diclofenac ophthalmic solution	2.5 mL	\$42.92	\$29.51
Voltaren® diclofenac ophthalmic solution	5 mL	\$70.03	\$48.16

In summary, bromfenac ophthalmic solution is used to reduce inflammation and pain following cataract extraction surgery. It represents an alternative to diclofenac ophthalmic solution.

References:

1. ISTA Pharmaceuticals. Bromfenac ophthalmic solution 0.09% (Xibrom) product information. Irvine CA: ISTA Pharmaeuticals; 2006.
2. Murray L, ed. *Red Book Pharmacy's Fundamental Reference*. Montvale NJ: Thompson PDR; 2006. L M, ed; No. June 2006 Update.

©2007, Department of Pharmacy Services, University of Utah Hospital, Salt Lake City, Utah. For more information, contact the Drug Information Service at 801-581-2073 or drug.info@hsc.utah.edu.