



Therapeutic Class ReviewSM

Nepafenac ophthalmic suspension 0.1% (NevanacTM)

and

Bromfenac ophthalmic solution 0.09% (XibromTM)

April 2006

New Product for Review:

bromfenac ophthalmic solution

(XibromTM) [Ista]

nepafenac ophthalmic suspension

(NevanacTM) [Alcon]

Dossier Provided by Manufacturer:

• Ista Pharmaceuticals: Yes

• Alcon Laboratories: Yes

Available Therapeutic Alternatives:

Preferred/Formulary	Non-Preferred/Non-Formulary
diclofenac sod ophthalmic solution (Voltaren [®]) [Novartis Pharmaceuticals]	bromfenac ophthalmic solution (Xibrom TM) [Ista]
ketorolac tromethamine ophthalmic solution Acular [®] ophthalmic solution [Allergan] Acular LS TM ophthalmic solution [Allergan] Acular [®] PF ophthalmic dropperette [Allergan]	nepafenac ophthalmic suspension (Nevanac TM) [Alcon]
flurbiprofen ophthalmic solution (Ocufen [®]) [Allergan] and generic	

Reason for Review:

Bromfenac ophthalmic solution (Xibrom) and nepafenac ophthalmic suspension (Nevanac) are two new ocular non-steroidal anti-inflammatory (NSAID) ophthalmic preparations marketed for use in patients with ocular inflammation post cataract extraction and lens replacement.

Executive Summary

- There is possibly useful evidence that bromfenac ophthalmic solution (Xibrom) is effective for the treatment of ocular inflammation due to cataract extraction and lens replacement.
- There is no useful evidence that either bromfenac ophthalmic solution (Xibrom) or nepafenac ophthalmic suspension (Nevanac) is more effective than existing formulary ophthalmic NSAID's.
- There is no useful evidence that either bromfenac ophthalmic solution (Xibrom) or nepafenac ophthalmic suspension (Nevanac) is safer than existing formulary ophthalmic NSAID's.
- Safety and efficacy of bromfenac ophthalmic solution (Xibrom) has not been established for patients less than 18 years of age.
- Safety and efficacy of nepafenac ophthalmic suspension (Nevanac) has not been established for patients less than 10 years of age.
- There was no evidence found that either bromfenac ophthalmic solution (Xibrom) or nepafenac ophthalmic suspension (Nevanac) significantly differs in safety or efficacy based on race, ethnicity, or gender.

Conclusion:

Bromfenac (Xibrom) and nepafenac (Nevanac) are non-preferred/non-formulary medications because there is no evidence of greater medical value over existing preferred/formulary options.

Products¹⁻³

Drug Products	FDA approval ^a	FDA approved indications	Usual Dose/Route	AWP ^{b,d}	Potential Off-label Uses ^c
diclofenac sod ophthalmic solution 0.1% (Voltaren [®])	03/91	Post-op inflammation following cataract extraction Post-op pain and photophobia following corneal refractive surgery	1 gtt QID beginning 1 day post-op x 14 days. 1-2 gtt 1hr pre-op, then QID x 3 days post-op	2.5ml \$44.71 5ml \$72.95	<ul style="list-style-type: none"> - Corneal abrasion - keratitis - laser photocoagulation - light intolerance - pain associated with foreign body - cystoid macular edema
flurbiprofen ophthalmic solution 0.03% (Ocufen [®])	12/86	Inhibition of intraoperative miosis.	1 gtt q30min 2hrs prior to surgery x 4 gtt.	2.5ml \$20.48 2.5ml (generic) \$8.73	<ul style="list-style-type: none"> - cystoid macular edema - inflammation post cataract surgery - uveitis syndrome
ketorolac tromethamine ophthalmic solution - (Acular [®] ophthalmic solution 0.5%) - (Acular LS [™] ophthalmic solution 0.4%) - (Acular [®] PF ophthalmic dropperette 0.5%)	11/92 05/03 11/97	<ul style="list-style-type: none"> - Seasonal allergic conjunctivitis - Post-op inflammation following cataract extraction - Post-op pain and stinging following corneal refractive surgery. - Post-op pain and photophobia following incisional refractive surgery 	1 gtt QID 1 gtt QID beginning 1 day post-op x 14 days. 1 gtt QID PRN for up to 4 days post-op 1 gtt QID PRN for up to 3 days post-op	3 ml \$42.93 5 ml \$71.53 10ml \$143.05 5ml \$71.53 12ml \$56.26	<ul style="list-style-type: none"> - cystoid macular edema - pain due to corneal abrasion
bromfenac ophthalmic solution 0.09% (Xibrom [™])	03/05	Post-op pain and inflammation following cataract extraction	1 gtt BID beginning 1 day post-op x 14 days.	5ml \$93.75	<ul style="list-style-type: none"> - conjunctivitis - blepharitis - episcleritis - schleritis
nepafenac ophthalmic suspension 0.1% (Nevanac [™])	08/05	Post-op pain and inflammation following cataract extraction	1 gtt TID beginning 1 day PRE-op, continued on day of surgery then 14 days post-op.	3ml \$78.75 (sufficient for full course of therapy)	

^a Date applies to approval date for the original brand name medication where there are now generics available.

^b Cost estimate based on AWP (average wholesale price) listed in First Data Bank as of January 27, 2006.

^c As listed in © 1974 - 2005 Thomson MICROMEDEX database or as referenced.

^d 5ml vial (3ml vial for Nevanac) is sufficient to complete the indicated course of therapy.

References

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6. Alcon Study # C-03-32. Product Dossier: Nevanac™ (nepafenac ophthalmic suspension 0.1%), Alcon Laboratories; Fort Worth, TX. Data reviewed February 1, 2006.
7. Alcon Study #C-02-53. Product Dossier: Nevanac™ (nepafenac ophthalmic suspension 0.1%), Alcon Laboratories; Fort Worth, TX. Data reviewed February 1, 2006.
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