FDA Approves Prolensa for Cataract Surgery Postop Pain

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Today the Food and Drug Administration (FDA) approved a new formulation of a once-daily nonsteroidal anti-inflammatory drug (NSAID) for the treatment of postoperative pain and inflammation in patients who have undergone cataract surgery. The newly approved 0.07% bromfenac ophthalmic solution (*Prolensa*, Bausch + Lomb) will likely replace the currently available 0.09% bromfenac ophthalmic solution.

Bromfenac is a critical ingredient in the formulation, as it facilitates ocular penetration of the NSAID. The newly approved drops are administered 1 drop daily beginning 1 day before surgery and continuing through the first 14 days postsurgery.

FDA approval was based on 2 randomized, double-masked studies in patients undergoing cataract surgery. The studies demonstrated the bromfenac ophthalmic solution 0.07% to be superior to vehicle for the reduction of inflammation and pain.

"The data show that once-daily dosing with Prolensa provides powerful and rapid control of inflammation and pain following cataract surgery, confirming the potency of this NSAID and the benefits of the new formulation," said Steven M. Silverstein, MD, founder of Silverstein Eye Centers in Kansas City, Missouri, in a Bausch + Lomb press release. "Prolensa reduces the amount of medication placed on the healing eye while maintaining a high degree of efficacy and ocular comfort."

The package insert will include warnings for sulfite allergic reactions, slow or delayed healing, and potential for cross-sensitivity. Adverse reactions (reported in from 3% to 8% of patients) include anterior chamber inflammation, foreign body sensation, eye pain, photophobia, and blurred vision.

Bausch + Lomb also offers a 0.09% bromfenac ophthalmic solution that was approved in 2010 for once-daily use. The newly approved formulation represents a new, modified ophthalmic formulation. The safety profile of the new formulation is consistent with the safety profile of the 0.09% formulation. It is expected, however, that patients will benefit from receiving the same amount of efficacy with a lower dose of medication.

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