

FDA Approves Preservative-Free Drug to Treat Glaucoma



On February 13, 2012, the U.S. Food and Drug Administration (FDA) approved Merck's once-daily, preservative-free medication eye drops to treat open-angle glaucoma or ocular hypertension.

ZIOPTAN™ (tafluprost ophthalmic solution) 0.0015%, is the first preservative-free prostaglandin analog ophthalmic solution. ZIOPTAN (pronounced zye-OP-tan) is approved for reducing elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension. Open-angle glaucoma is the most common form of glaucoma, while ocular hypertension is a condition characterized by an increase in pressure inside the eye.

“Prostaglandin analogs are often used as a first line of treatment to lower intraocular pressure in patients with open-angle glaucoma. The approval of ZIOPTAN will provide a new, effective option to lower IOP,” said George L. Spaeth, M.D., Wills Eye Institute, Philadelphia, “I anticipate using ZIOPTAN in many of these patients in my practice.”

ZIOPTAN may gradually change eyelashes in the treated eye. Changes include increased length, color, thickness, shape and number of lashes. Eyelash changes are usually reversible upon discontinuation of treatment. Other common side effects include increase pigmentation of the iris and redness in the eyes. The company warned that the eye solution should not be used by children or by pregnant women, and nursing women and people with macular swelling or edema should use the product “with caution.”

The FDA approval of ZIOPTAN was based on efficacy and safety results from five controlled clinical studies of up to two years in 905 patients. Both preservative-containing and preservative-free formulations of tafluprost were used in these clinical studies.

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