

One Year Post-Exclusivity Adverse Event Review: Levobetaxolol Hydrochloride Ophthalmic Solution

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Background Drug Information

Drug: Betaxon™ (levobetaxolol hydrochloride ophthalmic solution)

Therapeutic Category: Beta blocker

Sponsor: Alcon

Indication: for lowering intraocular pressure (IOP) in patients with chronic open-angle glaucoma or ocular hypertension

Original Market Approval: February 23, 2000

Pediatric Exclusivity Granted: June 28, 2006

Summary:

Levobetaxolol Hydrochloride Ophthalmic Solution

- Betaxon™ has never been marketed in the US.
- Betaxon™ is not currently being studied under an IND.
- There are no cases for any age group in the Adverse Event Reporting System as of August 30, 2007.
- This completes the one year post-exclusivity adverse event reporting.

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