



# U.S. Food and Drug Administration

Protecting and Promoting *Your* Health

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## Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

Search results from the "OB\_Rx" table for query on "203395."

Active Ingredient:	BROMFENAC SODIUM
Dosage Form ;Route:	SOLUTION/DROPS;OPHTHALMIC
Proprietary Name:	BROMFENAC SODIUM
Applicant:	HI-TECH PHARMACAL
Strength:	EQ 0.09% ACID
Application Number:	A203395
Product Number:	001
Approval Date:	Jan 22, 2014
Reference Listed Drug	No
RX/OTC/DISCN:	RX
TE Code:	<b>AT2</b>

Patent and Exclusivity Info for this product: [View](#)

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FDA/Center for Drug Evaluation and Research

Office of Generic Drugs

Division of Labeling and Program Support

Update Frequency:

Orange Book Data - **Monthly**

Generic Drug Product Information & Patent Information - **Daily**

Orange Book Data Updated Through October 2015

Patent and Generic Drug Product Data Last Updated November 13, 2015

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