



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 "076109."

Active Ingredient:	KETOROLAC TROMETHAMINE
Dosage Form;Route:	SOLUTION/DROPS;OPHTHALMIC
Proprietary Name:	KETOROLAC TROMETHAMINE
Applicant:	APOTEX INC
Strength:	0.5%
Application Number:	A076109
Product Number:	001
Approval Date:	Nov 5, 2009
Reference Listed Drug	No
RX/OTC/DISCN:	RX
TE Code:	AT

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 September 2015

Patent and Generic Drug Product Data Last Updated November 09, 2015

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U.S. Department of **Health & Human Services**

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