



U.S. Food and Drug Administration

Protecting and Promoting *Your* Health

[FDA Home](#)³ [Drug Databases](#)⁴ [Orange Book](#)⁵

Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

Search results from the "OB_Rx" table for query on "078553."

Active Ingredient:	DICLOFENAC SODIUM
Dosage Form;Route:	SOLUTION/DROPS;OPHTHALMIC
Proprietary Name:	DICLOFENAC SODIUM
Applicant:	NEXUS PHARMS
Strength:	0.1%
Application Number:	A078553
Product Number:	001
Approval Date:	Dec 28, 2007
Reference Listed Drug	No
RX/OTC/DISCN:	RX
TE Code:	AT

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

[Return to Electronic Orange Book Home Page](#)⁶

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

Links on this page:

1. <http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdomain>
2. <http://www.addthis.com/bookmark.php>
3. <http://www.fda.gov/default.htm>
4. <http://www.fda.gov/Drugs/InformationOnDrugs/default.htm>
5. [../default.cfm](#)
6. [../default.cfm](#)

Note: If you need help accessing information in different file formats, see [Instructions for Downloading Viewers and Players](#).

[Accessibility Contact](#) [FDA Careers](#) [FDA Basics](#) [FOIA No Fear Act](#) [Site Map](#) [Transparency Website](#) [Policies](#)

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
[Contact FDA](#)



[For Government For Press](#)

[Combination Products Advisory Committees Science & Research Regulatory Information Safety
Emergency Preparedness International Programs News & Events Training and Continuing Education
Inspections/Compliance State & Local Officials Consumers Industry Health Professionals FDA Archive](#)



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

Links on this page:

1. <http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdomain>
2. <http://www.addthis.com/bookmark.php>
3. <http://www.fda.gov/default.htm>
4. <http://www.fda.gov/Drugs/InformationOnDrugs/default.htm>
5. [../default.cfm](http://www.fda.gov/Drugs/InformationOnDrugs/default.htm)
6. [../default.cfm](http://www.fda.gov/Drugs/InformationOnDrugs/default.htm)