



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 "202435."

| | |
|-----------------------|---------------------------|
| Active Ingredient: | BROMFENAC SODIUM |
| Dosage Form ;Route: | SOLUTION/DROPS;OPHTHALMIC |
| Proprietary Name: | BROMFENAC SODIUM |
| Applicant: | APOTEX INC |
| Strength: | EQ 0.09% ACID |
| Application Number: | A202435 |
| Product Number: | 001 |
| Approval Date: | Jun 19, 2014 |
| Reference Listed Drug | No |
| RX/OTC/DISCN: | RX |
| TE Code: | AT1 |

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 October 2015

Patent and Generic Drug Product Data Last Updated November 13, 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/oc/default.cfm)
6. [../default.cfm](http://www.fda.gov/oc/default.cfm)