

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

Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

Orange Book Search Results on patent number '8859623' in the OB_Rx list.

Appl No	Prod No	Active Ingredient	Patent No	Patent Expire	Drug Substance Claim	Drug Product Claim	Patent Use Code	Delist Requested
N203510	001	PHENYLEPHRINE HYDROCHLORIDE	8859623	Nov 14, 2033			U -1594	
N203510	002	PHENYLEPHRINE HYDROCHLORIDE	8859623	Nov 14, 2033			U -1594	

Additional information:

1. Patents are published upon receipt by the Orange Book Staff and may not reflect the official receipt date as described in 21 CFR 314.53(d)(5).
2. Patents listed prior to August 18, 2003 are flagged with method of use claims only as applicable and submitted by the sponsor. These patents may not be flagged with respect to other claims which may apply.

[View a list of all patent use codes](#)

[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 March 2016

Patent and Generic Drug Product Data Last Updated May 04, 2016

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](#)
6. [../default.cfm](#)

[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 "203510."

Active Ingredient:	PHENYLEPHRINE HYDROCHLORIDE
Dosage Form;Route:	SOLUTION/DROPS;OPHTHALMIC
Proprietary Name:	PHENYLEPHRINE HYDROCHLORIDE
Applicant:	PARAGON BIOTECK
Strength:	2.5%
Application Number:	N203510
Product Number:	001
Approval Date:	Mar 21, 2013
Reference Listed Drug	Yes
RX/OTC/DISCN:	RX

TE Code:

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

Active Ingredient:	PHENYLEPHRINE HYDROCHLORIDE
Dosage Form;Route:	SOLUTION/DROPS;OPHTHALMIC
Proprietary Name:	PHENYLEPHRINE HYDROCHLORIDE
Applicant:	PARAGON BIOTECK
Strength:	10%
Application Number:	N203510
Product Number:	002
Approval Date:	Mar 21, 2013
Reference Listed Drug	Yes
RX/OTC/DISCN:	RX

TE Code:

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 March 2016

Patent and Generic Drug Product Data Last Updated May 04, 2016

Links on this page:

1. <http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain>
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](#)

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/default.cfm)
6. [../default.cfm](http://www.fda.gov/default.cfm)

[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 "203510."

Active Ingredient:	PHENYLEPHRINE HYDROCHLORIDE
Dosage Form;Route:	SOLUTION/DROPS;OPHTHALMIC
Proprietary Name:	PHENYLEPHRINE HYDROCHLORIDE
Applicant:	PARAGON BIOTECK
Strength:	2.5%
Application Number:	N203510
Product Number:	001
Approval Date:	Mar 21, 2013
Reference Listed Drug	Yes
RX/OTC/DISCN:	RX
TE Code:	

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

Active Ingredient:	PHENYLEPHRINE HYDROCHLORIDE
Dosage Form;Route:	SOLUTION/DROPS;OPHTHALMIC
Proprietary Name:	PHENYLEPHRINE HYDROCHLORIDE
Applicant:	PARAGON BIOTECK
Strength:	10%
Application Number:	N203510
Product Number:	002
Approval Date:	Mar 21, 2013
Reference Listed Drug	Yes
RX/OTC/DISCN:	RX
TE Code:	

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 March 2016

Patent and Generic Drug Product Data Last Updated May 04, 2016

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](#)

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.cfm)
6. [../default.cfm](http://www.fda.gov/Drugs/InformationOnDrugs/default.cfm)