

[FDA Home](#)³ [Drug Databases](#)⁴ [Drugs@FDA](#)⁵



FDA Approved Drug Products

[FAQ](#)⁶ | [Instructions](#)⁷ | [Glossary](#)⁸ | [Contact Us](#)⁹

[Email Link](#)

[Start Over](#) [Back to Overview](#)

Drug Details

Drug Name(s)	RESTASIS
FDA Application No.	(NDA) 050790
Active Ingredient(s)	CYCLOSPORINE
Company	ALLERGAN
Original Approval or Tentative Approval Date	December 23, 2002
Chemical Type	3 New dosage form
Review Classification	P Priority review drug

- [There are no Therapeutic Equivalents](#)
- [Approval History, Letters, Reviews, and Related Documents](#)
- [Label Information](#)

Products on Application (NDA) #050790
 Click on a column header to re-sort the table:

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	RLD	TE Code
RESTASIS	CYCLOSPORINE	0.05%	EMULSION;OPHTHALMIC	Prescription	Yes	None

[Back to Top](#) | [Back to Previous Page](#) | [Back to Drugs@FDA Home](#)

[Disclaimer](#)¹⁰

FDA/Center for Drug Evaluation and Research
 Office of Communications
 Division of Online Communications
 Update Frequency: Daily

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. <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm>
6. <http://www.fda.gov/Drugs/InformationOnDrugs/ucm075234.htm>
7. <http://www.fda.gov/Drugs/InformationOnDrugs/UCM079874>
8. <http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm>
9. <http://www.accessdata.fda.gov/scripts/email/cder/commentdrugcat.cfm>
10. <http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/default.htm#web>

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



Find authenticated court documents without watermarks at docketalarm.com.

10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Email 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



Links on this page: