

[FDA Home](#)<sup>3</sup> [Drug Databases](#)<sup>4</sup> [Drugs@FDA](#)<sup>5</sup>



FDA Approved Drug Products

[FAQ](#)<sup>6</sup> | [Instructions](#)<sup>7</sup> | [Glossary](#)<sup>8</sup> | [Contact Us](#)<sup>9</sup>

[Email Link](#)

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

**Drug Details**

<b>Drug Name(s)</b>	RESTASIS
<b>FDA Application No.</b>	(NDA) 050790
<b>Active Ingredient(s)</b>	CYCLOSPORINE
<b>Company</b>	ALLERGAN
<b>Original Approval or Tentative Approval Date</b>	December 23, 2002
<b>Chemical Type</b>	3 New dosage form
<b>Review Classification</b>	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](#)<sup>10</sup>

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](http://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: