

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



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

 [Email Link](#)

[Start Over](#)

[Back to Reports](#)<sup>10</sup>

## Drug Details

<b>Drug Name(s)</b>	<b>VISTOGARD</b>
<b>FDA Application No.</b>	<b>(NDA) 208159</b>
<b>Active Ingredient(s)</b>	<b>URIDINE TRIACETATE</b>
<b>Company</b>	<b>WELLSTAT THERAP</b>
<b>Original Approval or Tentative Approval Date</b>	<b>December 11, 2015</b>
<b>Chemical Type</b>	<b>10 New indication submitted as distinct NDA - not consolidated</b>

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

### Products on Application (NDA) #208159

**Click on a column header to re-sort the table:**

<a href="#">Drug Name</a>	<a href="#">Active Ingredients</a>	<a href="#">Strength</a>	<a href="#">Dosage Form/Route</a>	<a href="#">Marketing Status</a>	<a href="#">RLD</a>	<a href="#">TE Code</a>
VISTOGARD	URIDINE TRIACETATE	0.1G	GRANULE;ORAL	Prescription	TBD  <sup>11</sup>	None

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

[Disclaimer](#)<sup>12</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. [index.cfm?fuseaction=Reports.SetReport&reportselectdate=12/2015&rptname=1](http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Reports.SetReport&reportselectdate=12/2015&rptname=1)
11. <http://www.fda.gov/Drugs/InformationOnDrugs/UCM079862>
12. <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  
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. <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. <index.cfm?fuseaction=Reports.SetReport&reportselectdate=12/2015&rptname=1>
11. <http://www.fda.gov/Drugs/InformationOnDrugs/UCM079862>
12. <http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/default.htm#web>