

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



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

 [Email Link](#)

Start Over

Drug Details

Drug Name(s)	AVODART
FDA Application No.	(NDA) 021319
Active Ingredient(s)	DUTASTERIDE
Company	GLAXOSMITHKLINE
Original Approval or Tentative Approval Date	November 20, 2001
Chemical Type	1 New molecular entity (NME)
Review Classification	S Standard review drug

- [Therapeutic Equivalents](#)
- [Approval History, Letters, Reviews, and Related Documents](#)

- [Label Information](#)
- [Other Important Information from FDA](#) ¹⁰

Products on Application (NDA) #021319

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

Drug Name	Active Ingredients	Strength	Dosage Form / Route	Marketing Status	RLD	TE Code
AVODART	DUTASTERIDE	0.5MG	CAPSULE;ORAL	Prescription	Yes	AB

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

[Disclaimer](#)¹¹

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=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. <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/Drugs/DrugSafety/InformationbyDrugClass/ucm258424.htm>
11. <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)
[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: