

[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)	ZYTIGA
FDA Application No.	(NDA) 202379
Active Ingredient(s)	ABIRATERONE ACETATE
Company	JANSSEN BIOTECH
Original Approval or Tentative Approval Date	April 28, 2011
Chemical Type	1 New molecular entity (NME)
Review Classification	P Priority review drug

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

Products on Application (NDA) #202379

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

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	RLD	TE Code
ZYTIGA	ABIRATERONE ACETATE	250MG	TABLET;ORAL	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=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/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=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/AboutFDA/AboutThisWebsite/WebsitePolicies/default.htm#web>