



[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 Reports](#)¹⁰

Drug Details

Drug Name(s)	PRAMIPEXOLE DIHYDROCHLORIDE
FDA Application No.	(ANDA) 203615
Active Ingredient(s)	PRAMIPEXOLE DIHYDROCHLORIDE
Company	ACTAVIS ELIZABETH

- [Therapeutic Equivalents](#)
- [Approval History, Letters, Reviews, and Related Documents](#)
- **Labels are not available**

Products on Application (ANDA) #203615
Click on a column header to re-sort the table:

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	RLDTE Code
PRAMIPEXOLE DIHYDROCHLORIDE	PRAMIPEXOLE DIHYDROCHLORIDE	2.25MG	TABLET, EXTENDED RELEASE;ORAL	Prescription	No AB
PRAMIPEXOLE DIHYDROCHLORIDE	PRAMIPEXOLE DIHYDROCHLORIDE	3.75MG	TABLET, EXTENDED RELEASE;ORAL	None (Tentative Approval)	No None

[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=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&reportselctdate=10/2016&rptname=1](http://www.fda.gov/index.cfm?fuseaction=Reports.SetReport&reportselctdate=10/2016&rptname=1)
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)

[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. <index.cfm?fuseaction=Reports.SetReport&reportselectdate=10/2016&rptname=1>
11. <http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/default.htm#web>