

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



[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) 206156
Active Ingredient(s)	PRAMIPEXOLE DIHYDROCHLORIDE
Company	MACLEODS PHARMS LTD
Original Approval or Tentative Approval Date	June 24, 2016

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

Products on Application (ANDA) #206156

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	0.375MG	TABLET, EXTENDED RELEASE;ORAL	Prescription No	AB
PRAMIPEXOLE DIHYDROCHLORIDE	PRAMIPEXOLE DIHYDROCHLORIDE	0.75MG	TABLET, EXTENDED RELEASE;ORAL	Prescription No	AB
PRAMIPEXOLE DIHYDROCHLORIDE	PRAMIPEXOLE DIHYDROCHLORIDE	1.5MG	TABLET, EXTENDED RELEASE;ORAL	Prescription No	AB
PRAMIPEXOLE DIHYDROCHLORIDE	PRAMIPEXOLE DIHYDROCHLORIDE	2.25MG	TABLET, EXTENDED RELEASE;ORAL	Prescription No	AB
PRAMIPEXOLE DIHYDROCHLORIDE	PRAMIPEXOLE DIHYDROCHLORIDE	3MG	TABLET, EXTENDED RELEASE;ORAL	Prescription No	AB
PRAMIPEXOLE DIHYDROCHLORIDE	PRAMIPEXOLE DIHYDROCHLORIDE	4.5MG	TABLET, EXTENDED RELEASE;ORAL	Prescription No	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=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=06/2016&rptname=1](http://www.accessdata.fda.gov/scripts/email/cder/commentdrugcat.cfm?fuseaction=Reports.SetReport&reportselectdate=06/2016&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](#)



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=06/2016&rptname=1](http://www.accessdata.fda.gov/scripts/email/cder/commentdrugcat.cfm?fuseaction=Reports.SetReport&reportselectdate=06/2016&rptname=1)
11. <http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/default.htm#web>