

[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)	VRAYLAR
FDA Application No.	(NDA) 204370
Active Ingredient(s)	CARIPRAZINE
Company	FOREST LABS LLC
Original Approval or Tentative Approval Date	September 17, 2015

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

Products on Application (NDA) #204370

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

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	RLD	TE Code
VRAYLAR	CARIPRAZINE	1.5MG	CAPSULE;ORAL	Prescription	TBD  ¹¹	TBD  ¹²
VRAYLAR	CARIPRAZINE	3MG	CAPSULE;ORAL	Prescription	TBD  ¹³	TBD  ¹⁴
VRAYLAR	CARIPRAZINE	4.5MG	CAPSULE;ORAL	Prescription	TBD  ¹⁵	TBD  ¹⁶
VRAYLAR	CARIPRAZINE	6MG	CAPSULE;ORAL	Prescription	TBD  ¹⁷	TBD  ¹⁸

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

[Disclaimer](#)¹⁹

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=09/2015&rptname=1](http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Reports.SetReport&reportselectdate=09/2015&rptname=1)
11. <http://www.fda.gov/Drugs/InformationOnDrugs/UCM079862>

12. <http://www.fda.gov/Drugs/InformationOnDrugs/ucm075233.htm>
13. <http://www.fda.gov/Drugs/InformationOnDrugs/UCM079862>
14. <http://www.fda.gov/Drugs/InformationOnDrugs/ucm075233.htm>
15. <http://www.fda.gov/Drugs/InformationOnDrugs/UCM079862>
16. <http://www.fda.gov/Drugs/InformationOnDrugs/ucm075233.htm>
17. <http://www.fda.gov/Drugs/InformationOnDrugs/UCM079862>
18. <http://www.fda.gov/Drugs/InformationOnDrugs/ucm075233.htm>
19. <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=09/2015&rptname=1](http://www.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Reports.SetReport&reportselectdate=09/2015&rptname=1)
11. <http://www.fda.gov/Drugs/InformationOnDrugs/UCM079862>
12. <http://www.fda.gov/Drugs/InformationOnDrugs/ucm075233.htm>
13. <http://www.fda.gov/Drugs/InformationOnDrugs/UCM079862>
14. <http://www.fda.gov/Drugs/InformationOnDrugs/ucm075233.htm>
15. <http://www.fda.gov/Drugs/InformationOnDrugs/UCM079862>
16. <http://www.fda.gov/Drugs/InformationOnDrugs/ucm075233.htm>
17. <http://www.fda.gov/Drugs/InformationOnDrugs/UCM079862>
18. <http://www.fda.gov/Drugs/InformationOnDrugs/ucm075233.htm>
19. <http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/default.htm#web>