Drugs@FDA
FDA Approved Drug Products

Drug Details

Drug Name(s)	**REXULTI**
FDA Application No.	**(NDA) 205422**
Active Ingredient(s)	**BREXPIPRAZOLE**
Company	**OTSUKA PHARM CO LTD**
Original Approval or Tentative Approval Date	**July 10, 2015**
Chemical Type	**1 New molecular entity (NME)**
Review Classification	**S Standard review drug**

- **There are no Therapeutic Equivalents**
- **Label Information**
- **Approval History, Letters, Reviews, and Related Documents**

Products on Application (NDA) #205422
Click on a column header to re-sort the table:

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	RLD	TE Code
REXULTI	BREXPIPRAZOLE	0.25MG	TABLET;ORAL	Prescription	No	None
REXULTI	BREXPIPRAZOLE	0.5MG	TABLET;ORAL	Prescription	No	None
REXULTI	BREXPIPRAZOLE	1MG	TABLET;ORAL	Prescription	No	None
REXULTI	BREXPIPRAZOLE	2MG	TABLET;ORAL	Prescription	No	None
REXULTI	BREXPIPRAZOLE	3MG	TABLET;ORAL	Prescription	No	None
REXULTI	BREXPIPRAZOLE	4MG	TABLET;ORAL	Prescription	Yes	None

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. index.cfm?fuseaction=Reports.SetReport&reportselectdate=09/2016&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.

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=09/2016&rptname=1
11. http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/default.htm#web