Drug Details

Drug Name(s)	**KALETRA**
FDA Application No.	**(NDA) 021226**
Active Ingredient(s)	**LOPINAVIR; RITONAVIR**
Company	**ABBVIE**
Original Approval or Tentative Approval Date	**September 15, 2000**
Chemical Type	
Review Classification	**P Priority review drug**

- **There are no Therapeutic Equivalents**
- **Approval History, Letters, Reviews, and Related Documents**
- **Medication Guide**[12]
- **Label Information**
- **Other Important Information from FDA** [11]

Products on Application (NDA) #021226
Click on a column header to re-sort the table:

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	RLD	TE Code
KALETRA	LOPINAVIR; RITONAVIR	133.3MG; 33.3MG	CAPSULE;ORAL	Prescription	Yes	None

Back to Top | Back to Previous Page | Back to Drugs@FDA Home

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=06/2015&rptname=1
11. http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm246021.htm

12. http://www.fda.gov/downloads/Drugs/DrugSafety/UCM143461.pdf
13. 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.

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

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=06/2015&rptname=1
11. http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm246021.htm
12. http://www.fda.gov/downloads/Drugs/DrugSafety/UCM143461.pdf
13. http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/default.htm#web