Drug Details

Drug Name(s)	**DEXMEDETOMIDINE HYDROCHLORIDE**
FDA Application No.	**(ANDA) 204686**
Active Ingredient(s)	**DEXMEDETOMIDINE HYDROCHLORIDE**
Company	**ACTAVIS INC**
Original Approval or Tentative Approval Date	**October 18, 2016**

- **Therapeutic Equivalents**
- **Approval History, Letters, Reviews, and Related Documents**
- **Labels are not available**

Products on Application (ANDA) #204686
Click on a column header to re-sort the table:

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	RLD	TE Code
DEXMEDETOMIDINE HYDROCHLORIDE	DEXMEDETOMIDINE HYDROCHLORIDE	EQ 200MCG BASE/2ML (EQ 100MCG BASE/ML)	INJECTABLE;INJECTION	Prescription	No	AP

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=10/2016&rptname=1
11. http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/default.htm#web

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