Drugs@FDA
FDA Approved Drug Products

Drug Details

Drug Name(s)	**EXALGO**
FDA Application No.	**(NDA) 021217**
Active Ingredient(s)	**HYDROMORPHONE HYDROCHLORIDE**
Company	**MALLINCKRODT INC**
Original Approval or Tentative Approval Date	**March 1, 2010**
Chemical Type	**3 New dosage form**
Review Classification	**P Priority review drug**

- **Therapeutic Equivalents**
- **Approval History, Letters, Reviews, and Related Documents**
- **Medication Guide[12]**
- **Label Information**
- **REMS[11]**

Products on Application (NDA) #021217
Click on a column header to re-sort the table:

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	RLD	TE Code
EXALGO	HYDROMORPHONE HYDROCHLORIDE	8MG	TABLET, EXTENDED RELEASE;ORAL	Prescription	No	AB
EXALGO	HYDROMORPHONE HYDROCHLORIDE	12MG	TABLET, EXTENDED RELEASE;ORAL	Prescription	No	AB
EXALGO	HYDROMORPHONE HYDROCHLORIDE	16MG	TABLET, EXTENDED RELEASE;ORAL	Prescription	No	AB
EXALGO	HYDROMORPHONE HYDROCHLORIDE	32MG	TABLET, EXTENDED RELEASE;ORAL	Prescription	Yes	None

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

Disclaimer[13]

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/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM311290.pdf
12. http://www.accessdata.fda.gov/drugsatfda_docs/label/2012/021217s004mg.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.

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/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM311290.pdf
12. http://www.accessdata.fda.gov/drugsatfda_docs/label/2012/021217s004mg.pdf
13. http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/default.htm#web