Drug Details

Drug Name(s)	**PROZAC**
FDA Application No.	**(NDA) 018936**
Active Ingredient(s)	**FLUOXETINE HYDROCHLORIDE**
Company	**ELI LILLY AND CO**
Original Approval or Tentative Approval Date	**December 29, 1987**
Chemical Type	**1 New molecular entity (NME)**
Review Classification	**P Priority review drug**

- **Therapeutic Equivalents**
- **Approval History, Letters, Reviews, and Related Documents**
- **Medication Guide**[11]
- **Label Information**
- **Other Important Information from FDA** [10]

Products on Application (NDA) #018936
Click on a column header to re-sort the table:

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	RLD	TE Code
PROZAC	FLUOXETINE HYDROCHLORIDE	EQ 20MG BASE	CAPSULE;ORAL	Prescription	No	AB1
PROZAC	FLUOXETINE HYDROCHLORIDE	EQ 40MG BASE	CAPSULE;ORAL	Prescription	Yes	AB
PROZAC	FLUOXETINE HYDROCHLORIDE	EQ 60MG BASE	CAPSULE;ORAL	Discontinued	No	None
PROZAC	FLUOXETINE HYDROCHLORIDE	EQ 10MG BASE	CAPSULE;ORAL	Prescription	No	AB1
SARAFEM	FLUOXETINE HYDROCHLORIDE	EQ 10MG BASE **Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**	CAPSULE;ORAL	Discontinued	No	None
SARAFEM	FLUOXETINE HYDROCHLORIDE	EQ 20MG BASE **Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**	CAPSULE;ORAL	Discontinued	No	None

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