Drug Details

Drug Name(s)	**DURAGESIC-25**
FDA Application No.	**(NDA) 019813**
Active Ingredient(s)	**FENTANYL**
Company	**JANSSEN PHARMS**
Original Approval or Tentative Approval Date	**August 7, 1990**
Chemical Type	
Review Classification	**S Standard review drug**

- **Therapeutic Equivalents**
- **Approval History, Letters, Reviews, and Related Documents**
- **REMS**[12]
- **Medication Guide**[14]
- **Label Information**
- **REMS**[11]
- **Other Important Information from FDA** [13]

Products on Application (NDA) #019813
Click on a column header to re-sort the table:

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	RLD	TE Code
DURAGESIC-100	FENTANYL	100MCG/HR	FILM, EXTENDED RELEASE;TRANSDERMAL	Prescription	No	AB
DURAGESIC-12	FENTANYL	12.5MCG/HR	FILM, EXTENDED RELEASE;TRANSDERMAL	Prescription	No	AB
DURAGESIC-25	FENTANYL	25MCG/HR	FILM, EXTENDED RELEASE;TRANSDERMAL	Prescription	Yes	AB
DURAGESIC-50	FENTANYL	50MCG/HR	FILM, EXTENDED RELEASE;TRANSDERMAL	Prescription	No	AB
DURAGESIC-75	FENTANYL	75MCG/HR	FILM, EXTENDED RELEASE;TRANSDERMAL	Prescription	No	AB

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