

FENTANYL CITRATE, BUPIVACAINE HCL - fentanyl citrate, bupivacaine hcl injection, solution

Cantrell Drug Company

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, [click here](#).

Fentanyl Citrate 2 mcg/mL & Bupivacaine HCl 0.125% in 0.9% Sodium Chloride 250 mL Bag

fentaNYL 2 mcg/mL **&** **Bupivacaine 0.125%** HCl in 0.9% Sodium Chloride 250 mL* Bag

Epidural Use Only

Total Dose: (500 mcg/312.5 mg)/ 250 mL*

*Prefilled 150 mL Bag with 250 mL Total Volume

Store at Room Temperature. Protect from Light.

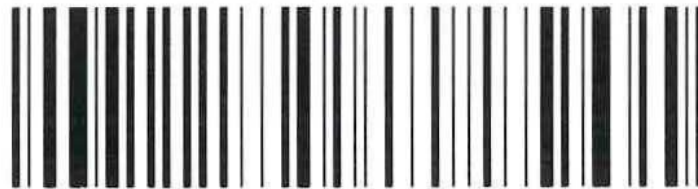
Preservative Free Injection Solution.

Single-Dose Bag. Hospital/Office Use Only.



NDC: 52533-080-61

Rx Only



(01) 0 0352533 08061 6

**Each mL Contains: Fentanyl Citrate 2 mcg (eq to fentanyl base),
Bupivacaine HCl 1.25 mg, Sodium Chloride 9 mg.
pH adjusters: Hydrochloric Acid/Sodium Hydroxide.**

Outsourced Compounded Drug. Not for Resale.

LOT: XXXXXX

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BUD:

CMPD Date: 03/13



CANTRELL DRUG COMPANY

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Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:52533-080
Route of Administration	EPIDURAL	DEA Schedule	CII

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Fentanyl Citrate (UNII: MUN5LYG46H) (Fentanyl - UNII:UF599785JZ)	Fentanyl	2 ug in 1 mL
BUPIVACAINE HYDROCHLORIDE (UNII: 7TQO7W3VT8) (BUPIVACAINE - UNII:Y8335394RO)	BUPIVACAINE HYDROCHLORIDE ANHYDROUS	1.25 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Sodium Chloride (UNII: 451W47IQ8X)	9 mg in 1 mL
Water (UNII: 059QF0KO0R)	

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
May contain	HYDROCHLORIC ACID (UNII: QTT17582CB)	
May contain	SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52533-080-61	250 mL in 1 BAG		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		08/16/2012	

Labeler - Cantrell Drug Company (035545763)

Revised: 8/2014

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