

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 125 mL Bag

fentaNYL citrate 2 mcg/mL & Bupivacaine HCl 0.125% in 0.9% Sodium Chloride 125 mL* Bag

Epidural Use Only

Total Dose: (250 mcg/156.25 mg)/125 mL*

*Prefilled 100 mL Bag with 125 mL Total Volume

Store at Room Temperature. Protect from Light.

Preservative Free Injection Solution. Single-Dose Bag.

Each mL Contains: Fentanyl Citrate 2 mcg (eq to fentanyl base), Bupivacaine HCl 1.25 mg, Sodium Chloride 9 mg. pH adj: HCl/NaOH.

Rx Only



NDC: 52533-080-64



(01) 0 0352533 08064 7

Hospital/Office
Use Only.

Lot: XXXXX

BUD:

CMPD Date: 03/13

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Outsourced Compounded Drug. Not for Resale.
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FENTANYL CITRATE, BUPIVACAINE HCL

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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
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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:52533-080-64	125 mL in 1 BAG		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		09/17/2013	

Labeler - Cantrell Drug Company (035545763)

Revised: 1/2015

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