

HYDROMORPHONE HCL - hydromorphone 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.

Hydromorphone HCl 1 mg/mL in 0.9% Sodium Chloride 50 mL Syringe

HYDROmorphone _{HCl} **50 mg/50 mL**
in 0.9% Sodium Chloride

HYDROmorphone 1 mg/mL

LOT: xxxxx **(1 mg/mL)**
BUD:
Compounded Date: 01/13 **Qty: 50 mL**

Store at Room Temperature. Protect from Light.
Preservative Free. Single-Dose Syringe.
Injection Solution for Slow IV Use.



Each mL: Hydromorphone HCl 1 mg, Sodium Chloride 9 mg. pH adj: HCl/NaOH.

NDC: 52533-006-04 Hospital/Office Use Only



Rx Only



C-II

00001

Outsourced Compounded Drug: Not for Resale.
Cantrell Drug Co. 7321 Cantrell Road Little Rock, AR
877-666-5222 www.cantrelldrug.com

• WARNINGS AND PRECAUTIONS

Outsourced Compounded Drug. Not for Resale. Hospital/Office Use Only.

• ADVERSE EVENTS

To facilitate Adverse Event Reporting: www.fda.gov/medwatch or 1-800-FDA-1088.

• HOW SUPPLIED

Contains 50 mL (50 mg) of Hydromorphone HCl 1 mg/mL in 0.9% Sodium Chloride in a 50 mL Single-

Dose Syringe.

This product is Sterile, Nonpyrogenic, Preservative Free, Isotonic, and Latex Free.

• **INGREDIENTS**

Each 1 mL contains Hydromorphone HCl 1 mg, Sodium Chloride 9 mg. May contain Hydrochloric Acid and/or Sodium Hydroxide for pH adjustment.

• **STORAGE AND HANDLING**

Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature]. Protect from freezing. Protect from Light.

• **DOSAGE AND ADMINISTRATION.**

FOR SLOW INTRAVENOUS USE. PRESERVATIVE FREE INJECTION SOLUTION.

Rx Only

Rev. 03/15

CANTRELL DRUG COMPANY

LITTLE ROCK, AR 72207

HYDROMORPHONE HCL			
hydromorphone hcl injection, solution			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:52533-006
Route of Administration	INTRAVENOUS	DEA Schedule	CII
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
HYDROMORPHONE HYDROCHLORIDE (UNII: L960UP2KRW) (HYDROMORPHONE - UNII:Q812464R06)		HYDROMORPHONE HYDROCHLORIDE	1 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:52533-006-04	50 mL in 1 SYRINGE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		08/30/2012	

Labeler - Cantrell Drug Company (035545763)

Revised: 3/2015

Cantrell Drug Company