

AMIODARONE HCL - amiodarone 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.

Amiodarone HCl 450 mg Added to 5% Dextrose 250 mL Bag

Amiodarone 450 mg

HCl

Added to 5% Dextrose 250 mL* Bag (1.8 mg/mL*)

***Volume and Concentration Exclude Manufacturer Overfill.**

Store at Room Temperature. Protect from Light.
Contains Preservatives. Single-Dose Bag.
Recommend In-Line Filter During Administration.
Injection Solution for IV Use.

Each mL Contains: Amiodarone HCl 1.8 mg; Polysorbate 80, 3.6 mg;
Benzyl Alcohol 0.73 mg; Dextrose 50 mg.

NDC: 52533-101-58

**HIGH
ALERT**



Rx Only

Hospital/Office Use Only

Outsourced Compounded Drug. Not for Resale

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LOT: xxxxxx

BUD:

CMPD Date: 03/13



AMIODARONE HCL

amiodarone hcl injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:52533-101
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AMIODARONE HYDROCHLORIDE (UNII: 976728SY6Z) (Amiodarone - UNII:N3RQ532IUT)	AMIODARONE HYDROCHLORIDE	1.8 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Dextrose (UNII: IY9XDZ35W2)	50 mg in 1 mL
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	3.6 mg in 1 mL
BENZYL ALCOHOL (UNII: LKG8494WBH)	0.73 mg in 1 mL
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52533-101-58	250 mL in 1 BAG		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		08/01/2011	

Labeler - Cantrell Drug Company (035545763)

Revised: 8/2014

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