CARDIOVASCULAR PROCEDURE KIT-Centurion Medical Products

Cardiovas cular Procedure Kit

DESCRIPTION

Lidocaine Hydrochloride Injection, USP is a sterile, nonpyrogenic solution of lidocaine hydrochloride in water for injection for parenteral administration in various concentrations. Multiple dose vials contain 0.1% methylparaben added as preservative. May contain sodium hydroxide and/or hydrochloric acid for pH adjustment. The pH is 6.5 (5.0 to 7.0). Lidocaine is a local anesthetic of the amide type. Lidocaine Hydrochloride, USP is a white powder freely soluable in water. The molecular weight is 288.82. The semi rigid vial used for the plastic vials is fabricated from a specially formulated plyolefin. It is a copolymer of ethylene of propylene. The safety of the plastic vials has been confirmed by tests in animals according to USP biological standards for plastic containers. The container requires no vapor barrier to maintain the proper drug concentration.

Cardiovas cular Procedure Kit Primary Label



032312G

Example Cardiovascular Kit

Reorder XXXXXXX

CONTENTS:

- 1 STERILE EXAMPLE CARDIOVASCULAR KIT
- 1 STERILE LIDOCAINE HCI SOLUTION

Example Only - Components & Title May Vary



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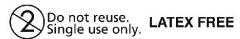


N/A



NOTES:

Store between 20-25°C (68-77°F).





CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

CENTURION MEDICAL PRODUCTS CORP. | WILLIAMSTON | MI | 48895 USA | 800.248.4058 | www.centurionmp.com

MM1

Lidocaine Label



MM1

CARDIOVASCULAR PROCEDURE KIT

cardiovascular procedure kit kit

Product Information

Product Type MEDICAL DEVICE **Item Code (Source)** NHRIC:24840-1110

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NHRIC:24840-1110-2	10 in 1 CASE		
1 NHRIC:24840-1110-1	1 in 1 PACKAGE, COMBINATION		

Quantity of Parts				
Part #	Package Quantity	Total Product Quantity		
Part 1	1 VIAL, MULTI-DOSE	50 mL		

Part 1 of 1

LIDOCAINE HYDROCHLORIDE

lidocaine hydrochloride anhydrous injection, solution

Product Information		
Item Code (Source)	NDC:0409-4276	
Route of Administration	INFILTRATION	

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
LIDO CAINE HYDRO CHLO RIDE ANHYDRO US (UNII: EC2CNF7XFP) (LIDO CAINE - UNII:98 PI20 0 9 8 7)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	10 mg in 1 mL		

Inactive Ingredients				
Ingredient Name	Strength			
SODIUM CHLORIDE (UNII: 451W47IQ8X)	7 mg in 1 mL			
WATER (UNII: 059QF0KO0R)				
SO DIUM HYDRO XIDE (UNII: 55X0 4QC32I)				
HYDRO CHLORIC ACID (UNII: QTT17582CB)				
METHYLPARABEN (UNII: A218 C7H19 T)				

F	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0409-4276-02	50 mL in 1 VIAL, MULTI-DOSE		

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
ANDA	ANDA088299	03/30/2010			

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
exempt device	OEZ	0 1/0 1/20 12			

Labeler - Centurion Medical Products (017246562)

Establishment				
Name	Address	ID/FEI	Business Operations	
Centurion Medical Products		017246562	manufacture, repack	

Establishment				
Name	Address	ID/FEI	Business Operations	
Centurion Medical Products		148522279	manufacture, repack	

Establishment				
Name	Address	ID/FEI	Business Operations	
Centurion Medical Products		626660810	manufacture, repack	

Establishment			
Name	Address	ID/FEI	Business Operations
Hospira, Inc		093132819	manufacture

Revised: 6/2012 Centurion Medical Products