#### CARDIOVASCULAR PROCEDURE KIT-Centurion Medical Products

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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% of 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 colecular weight is 288.82.

#### Cardiovas cular Procedure Kit Primary Label

## **CENTURION®**

030712G

# Example Cardiovascular Kit

Reorder



#### **CONTENTS:**

- 1 CSR WRAP
- 1 FENESTRATED DRAPE
- 1 PAIR of GLOVES
- 1 DRAPE
- 2 GAUZE SPONGES
- 1 AMPULE CRACKER
- 1 LIDOCAINE HCI SOLUTION
- 2 SYRINGES[1]
- 1 FILTER NEEDLE [1,2]
- 1 SAFETY NEEDLE [1]
- 1 NEEDLE CUBE
- 1 PANEL OF LABELS
- 1 TRAY

#### **Example Only - Components & Title May Vary**

LOT

00000



N/A



NOTES: 1) Non-Pyrogenic. 2) Not for injection. Store between 20-25°C (68-77°F).





Do not use if package is open or damaged.



LATEX FREE



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



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#### CARDIOVASCULAR PROCEDURE KIT

cardiovascular procedure kit kit

P	ro	d	uct	Inf	o	rma	ation

Product Type

MEDICAL DEVICE

Item Code (Source)

NHRIC:24840-1101

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:24840-1101-2	10 in 1 CASE		
1	NHRIC:24840-1101-1	1 in 1 PACKAGE, COMBINATION		

#### **Quantity of Parts**

Part #	Package Quantity	Total Product Quantity
Part 1	1 AMPULE	5 mL

#### Part 1 of 1

#### LIDOCAINE HYDROCHLORIDE

lidocaine hydrochloride anhydrous injection, solution

#### **Product Information**

Item Code (Source)	NDC:0409-4713
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)				
SODIUM HYDROXIDE (UNII: 55X04QC32I)				
HYDRO CHLO RIC ACID (UNII: QTT17582CB)				

	Packaging					
1	# Item Code	Package Description	Marketing Start Date	Marketing End Date		
	NDC:0409-4713-65	5 mL in 1 AMPULE				

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
ANDA	ANDA080408	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