

CARDIOVASCULAR PROCEDURE KIT-
Centurion Medical Products

Cardiovascular ProcedureKit

Drug Description

**AQUEOUS SOLUTIONS FOR INFILTRATION
AND NERVE BLOCK**

Ampul

Plastic Multiple-dose Fliptop Vial

Glass Teartop Vial

Rx only

DESCRIPTION

Lidocaine Hydrochloride Injection, USP is a sterile, nonpyrogenic solution of lidocaine hydrochloride in water for injection for parenteral administration in various concentrations with characteristics as follows:

Concentration 0.5% 1% 1.5% 2%

mg/mL lidocaine HCl (anhyd.) 5 10 15 20

mg/mL sodium chloride 8 7 6.5 6

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 chemically designated 2-(diethylamino)-N-(2,6-dimethylphenyl)-acetamide monohydrochloride monohydrate, a white powder freely soluble in water. The molecular weight is 288.82.

Cardiovascular Procedure Kit - Primary Label

MM1

CENTURION®

030712G

Example
Cardiovascular Kit

Reorder

XXXXXXXXX

CONTENTS:

- 1 CSR WRAP
- 1 FENESTRATED DRAPE
- 1 PAIR of GLOVES
- 1 DRAPE
- 2 GAUZE SPONGES
- 1 AMPULE CRACKER
- 1 LIDOCAINE HCl 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



(01) 0 0653160 00000 9

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

STERILE **EO**  Do not use if package is open or damaged.  Do not reuse. Single use only. **LATEX FREE**  Consult instructions for use.

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

CARDIOVASCULAR PROCEDURE KIT

cardiovascular procedure kit kit

Product Information

Product Type	MEDICAL DEVICE	Item Code (Source)	NHRIC:24840-1102
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:24840-1102-2	10 in 1 CASE		
1	NHRIC:24840-1102-1	1 in 1 PACKAGE, COMBINATION		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 AMPULE	2 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
LIDOCAINE HYDROCHLORIDE ANHYDROUS (UNII: EC2CNF7XFP) (Lidocaine - UNII:98PI200987)	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)	
Hydrochloric Acid (UNII: QTT17582CB)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0409-4713-32	2 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	03/02/2012	

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		093132819	manufacture