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% 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 molecular weight is 288.82. The semi-rigid vial used for the plastic vials is fabricated from a specially formulated polyolefin. It is a copolymer of ethylene and propylene.

Cardiovas cular Kit Primary Label

CENTURION®

032312G

Example Cardiovascular Kit

Reorder



CONTENTS:

1 STERILE EXAMPLE CARDIOVASCULAR KIT

1 STERILE LIDOCAINE HCI SOLUTION

Example Only - Components & Title May Vary

LOT

000000000



N/A



(01) 1 0653160 00000 6

NOTES:

Store between 20-25°C (68-77°F).



Do not reuse. Single use only.



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

Lidocaine

20 mL Multiple-dose

HOSPIRA, INC., LAKE FOREST, IL 60045 USA

FOR INFILTRATION AND NERVE BLOCK. NOT epidural and caudal use. Contains preservative. mL contains lidocaine hydrochloride, anhydrous 10 mg; sodium chloride 7 mg; methylparaben 1 mg added as preservative. May contain HCl and/or NaOH for pH adjustment. pH 6.5 (5.0 to 7.0). Sterile, nonpyrogenic. Usual dosage: See insert. Store at 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature.]

R only

RL-1258 (3/05)



CARDIOVASCULAR PROCEDURE KIT

cardiovascular procedure kit kit

Product Information

Product Type MEDICAL DEVICE Item Code (Source) NHRIC:24840-1108

I	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:24840-1108-2	10 in 1 CASE		
1	NHRIC:24840-1108-1	1 in 1 PACKAGE, COMBINATION		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 VIAL, MULTI-DOSE	20 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 98 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 CHLO RIC ACID (UNII: QTT17582CB)				
METHYLPARABEN (UNII: A2I8 C7HI9 T)	1 mg in 1 mL			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1 NDC:0409-4276-01 20 mL in 1 VIAL, MULTI-DO
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Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	A NID A 0 0 0 20 0	0.2/20/2010	

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

Listablishinelle			
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

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

Revised: 8/2012 Centurion Medical Products