CARDIOVASCULAR PROCEDURE KIT-Centurion Medical Products

Cardiovas cular Procedure Kit

Cardiovas cular Procedure Kit - Primary Label

MM1

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



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N/A

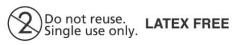


NOTES: 1) Non-Pyrogenic. 2) Not for injection. Store between 20-25°C (68-77°F).





Do not use if package is open or damaged.





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

DESCRIPTION

Xylocaine (lidocaine HCl) Injections are sterile, nonpyrogenic, aqueous solutions that contain a local anesthetic agent with or without epinephrine and are administered parenterally by injection.

Xylocaine solutions contain lidocaine HCl, which is chemically designated as acetamide, 2-(diethylamino)-N-(2,6-dimethylphenyl)-, monohydrochloride and has the molecular wt. 270.8.

Epinephrine is (-) -3, 4-Dihydroxy- α -[(methylamino) methyl] benzyl alcohol and has the molecular wt. 183.21.

Xylocaine MPF is a sterile, nonpyrogenic, isotonic solution containing sodium chloride. Xylocaine in multiple dose vials: Each mL also contains 1 mg methylparaben as antiseptic preservative. The pH of these solutions is adjusted to approximately 6.5 (5.0 to 7.0) with sodium hydroxide and/or hydrochloric acid.

Xylocaine MPF with Epinephrine is a sterile, nonpyrogenic, isotonic solution containing sodium chloride. Each mL contains lidocaine hydrochloride and epinephrine, with 0.5 mg sodium metabisulfite as an antioxidant and 0.2 mg citric acid as a stabilizer. Xylocaine with Epinephrine in multiple dose vials: Each mL also contains 1 mg methylparaben as antiseptic preservative. The pH of these solutions is adjusted to approximately 4.5 (3.3 to 5.5) with sodium hydroxide and/or hydrochloric acid.

CARDIOVASCULAR PROCEDURE KIT cardiovascular procedure kit kit **Product Information** Product Type MEDICAL DEVICE Item Code (Source) NHRIC:24840-1106

Packaging

#	tem Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:24840-1106-2	10 in 1 CASE		
1	NHRIC:24840-1106-1	1 in 1 PACKAGE, COMBINATION		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 VIAL, MULTI-DOSE	10 mL

Part 1 of 1

XYLOCAINE

lidocaine hydrochloride injection, solution

Product Information

Item Code (Source)	NDC:63323-486
Route of Administration	INFILTRATION

Active Ingredient/Active Moiety

8			
Ingredient Name	Basis of Strength	Strength	
LIDO CAINE HYDRO CHLO RIDE (UNII: V13007Z41A) (LIDO CAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE	20 mg in 1 mL	

Inactive Ingredients				
Ingredient Name	Strength			
SODIUM CHLORIDE (UNII: 451W47IQ8X)	6 mg in 1 mL			
METHYLPARABEN (UNII: A2I8C7HI9T)	1 mg in 1 mL			
SO DIUM HYDRO XIDE (UNII: 55X04QC32I)				
HYDRO CHLO RIC ACID (UNII: QTT17582CB)				

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:63323-486-17	10 mL in 1 VIAL, MULTI-DOSE				

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
NDA	NDA006488	08/12/2010		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
exempt device	OEZ	0 1/0 1/20 11	

Labeler - Centurion Medical Products (017246562)

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

Establishment				
Name	Address	ID/FEI	Business Operations	
APP Pharmaceuticals, LLC		023648251	manufacture	

Revised: 3/2012 Centurion Medical Products