

**CARDIOVASCULAR PROCEDURE KIT -
Centurion Medical Products**

Cardiovascular Procedure Kit

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

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)

NHRC:24840-1106

Packaging

#	Item 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				
Ingredient Name			Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)			LIDOCAINE HYDROCHLORIDE	20 mg in 1 mL
Inactive Ingredients				
Ingredient Name			Strength	
SODIUM CHLORIDE (UNII: 451W47IQ8X)			6 mg in 1 mL	
METHYL PARABEN (UNII: A2I8C7HI9T)			1 mg in 1 mL	
SODIUM HYDROXIDE (UNII: 55X04QC32I)				
HYDROCHLORIC ACID (UNII: QTT17582CB)				
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	01/01/2011	

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