GENERAL SURGERY KIT- general surgery tray (kit) Centurion Medical Products

General Surgery Kit

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.

General Surgery Kit - Primary Label

MM1

CENTURION®

030712G

Example General Surgery Tray

Reorder XXXXXX

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



Consult

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

general surgery tray (kit) kit

Product Information

Product Type MEDICAL DEVICE Item Code (Source) NHRIC:24840-1500

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NHRIC:24840-1500	10 in 1 CASE				
1	NHRIC:24840-1500-15	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			
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: 059 QF0 KO0 R)				
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 I					
ANDA	03/30/2010				
Marketing Information					
		Mandarda Charle			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
Marketing Category exempt device	Application Number or Monograph Citation LRO	03/02/2012	Marketing End Date		

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		
Ho spira		093132819	manufacture		

Revised: 3/2012 Centurion Medical Products