

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 Flip-top 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). See HOW SUPPLIED section for various sizes and strengths.

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. It has the following structural formula:

General Surgery Kit - Primary Label

MM1

CENTURION®

061810G

General Surgery Kit

Reorder
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CONTENTS:

- 1 CSR WRAP
- 1 FENESTRATED DRAPE
- 1 DRAPE
- 2 ALCOHOL PREP PADS
- 2 GAUZE SPONGES
- 1 AMPULE CRACKER
- 1 LIDOCAINE HCl SOLUTION
- 1 SYRINGE⁽¹⁾
- 1 FILTER NEEDLE^(1,2)
- 1 SAFETY NEEDLE⁽¹⁾
- 1 NEEDLE CUBE
- 1 PANEL of LABELS
- 1 TRAY

LOT 00000

N/A



(01) 1 0653160 00000 6

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

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GENERAL SURGERY KIT

general surgery tray (kit) kit

Product Information

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

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:24840-1500	10 in 1 CASE		
1	NHRIC:24840-1500-10	1 in 1 PACKAGE, COMBINATION		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 AMPULE	5 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:0409-4713-65	5 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	LRO	02/20/2012	

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

Revised: 2/2012

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