

OBGYN PROCEDURE KIT - obstetrical kit
Centurion Medical Products

OBGYN 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% 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 soluble 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. The safety of the plastic has been confirmed by tests in animals according to USP biological standards for plastic containers. The container requires no vapor barrier to maintain the proper drug concentration.

OBGYN Procedure Kit Primary Label

CENTURION®

030712G

**Example OB/GYN
Procedure Tray**

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

MM1

Lidocaine Label



MM1

OBGYN PROCEDURE KIT

obstetrical kit kit

Product Information

Product Type	MEDICAL DEVICE	Item Code (Source)	NHRIC:24840-1701
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:24840-1701-2	10 in 1 CASE		
1	NHRIC:24840-1701-1	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
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ANDA	ANDA080408	03/30/2010	
Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
exempt device	OKV	01/01/2012	

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: 5/2012

Centurion Medical Products