

OBGYN PROCEDURE KIT - obstetrical kit
Centurion Medical Products

OBGYN Procedure Kit

DESCRIPTION

Lidocaine Hydrochloride Injection, USP is a sterile, nonpyrogenic solution of an antiarrhythmic agent administered intravenously by either direct injection or continuous infusion. It is available in the following concentration: 5mL (100 mg), 6.0 (5.0 to 7.0) pH. May contain sodium hydroxide and/or hydrochloric acid for pH adjustment. Injections containing 10 mg/mL (1%) contain sodium chloride 7 mg and injections containing 20 mg/mL (2%) lidocaine hydrochloride contain sodium chloride 6 mg to adjust tonicity. Single dose solutions contain no preservative and unused portions must be discarded after use. Lidocaine Hydrochloride, USP is a white powder freely soluble in water. The molecular weight is 288.82. The plastic syringe is molded from a specially formulated polypropylene. Water permeates from inside the container at an extremely slow rate which will have an insignificant effect on solution concentration over the expected shelf life. Solutions in contact with the plastic container may leach out certain chemical components from the plastic in very small amounts; however, biological testing was supportive of the safety of the syringe material.

OBGYN Procedure Kit Primary Label

CENTURION®

032312G

**Example OB/GYN
Procedure Tray**

Reorder

XXXXXXXXXX

CONTENTS:

1 STERILE EXAMPLE OB/GYN PROCEDURE TRAY

1 STERILE LIDOCAINE INJECTION SOLUTION

Example Only - Components & Title May Vary

LOT 0000000000



N/A



(01) 1 0653160 00000 6

NOTES:

Store between 20-25°C (68-77°F).



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

1% LIDOCAINE HCl 50 mg (10 mg/mL)

Approx.
mL

1

2

3

4

5

Approx.
mg

10

20

30

40

50

5 mL Single-dose

NDC 0409-9137-05

1% LIDOCAINE HCl Inj., USP

50 mg (10 mg/mL)

IV. use for Ventricular Arrhythmias. Rx only

Usual dosage: See insert

Sterile, nonpyrogenic, pH 8.0 (5.0 to 7.0).

Hospira Inc., Lake Forest, IL 60045 USA



RL-0181 (5/04)



(01) 0 090409 913705 1

MM1

OBGYN PROCEDURE KIT

obstetrical kit kit

Product Information

Product Type

MEDICAL DEVICE

Item Code (Source)

NHRC:24840-1705

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:24840-1705-2	10 in 1 CASE		
1	NHRIC:24840-1705-1	1 in 1 PACKAGE, COMBINATION		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 SYRINGE, PLASTIC	5 mL

Part 1 of 1

LIDOCAINE HYDROCHLORIDE

lidocaine hydrochloride injection, solution

Product Information

Item Code (Source)	NDC:0409-9137
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE	10 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0409-9137-05	5 mL in 1 SYRINGE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040302	11/29/2010	

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