OBGYN PROCEDURE KIT- obstetrical kit Centurion Medical Products

OBGYN Procedure Kit

DESCRIPTION

Lidocaine Hydrochloride Injection, USP is a sterile, nonpyrogenic solution of an antriarrhythmic agent administered interavenously 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 hydrocholoric 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 soluable 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 XXXXXXX

CONTENTS:

- 1 STERILE EXAMPLE OB/GYN PROCEDURE TRAY
- 1 STERILE LIDOCAINE INJECTION SOLUTION

Example Only - Components & Title May Vary



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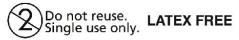
N/A



(01) 1 0653160 00000 6

NOTES:

Store between 20-25°C (68-77°F).





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 MEDIC.

MEDICAL DEVICE

Item Code (Source)

NHRIC:24840-1705

P	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				

Quan	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	
LIDO CAINE HYDRO CHLO RIDE (UNII: V13007Z41A) (LIDO CAINE - UNII: 98PI200987)	LIDOCAINE HYDROCHLORIDE	10 mg in 1 mL	

Inactive Ingredients				
Ingredient Name	Strength			
SO DIUM HYDRO XIDE (UNII: 55X04QC32I)				
HYDRO CHLORIC 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	0 1/0 1/20 12		

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