CARDIOVASCULAR PROCEDURE KIT-Centurion Medical Products

Cardiovas cular Procedure 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.

Cardiovas cular Procedure Kit - Primary Label

MM1

CENTURION®

030712G

Example Cardiovascular Kit

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 instructions

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

cardiovascular procedure kit kit

Product Information

Product Type MEDICAL DEVICE Item Code (Source) NHRIC:24840-1104

| F | Packaging | | | | |
|---|--------------------|-----------------------------|----------------------|--------------------|--|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date | |
| 1 | NHRIC:24840-1104-2 | 10 in 1 CASE | | | |
| 1 | NHRIC:24840-1104-1 | 1 in 1 PACKAGE, COMBINATION | | | |

Quantity of Parts

| Part # | Package Quantity | Total Product Quantity |
|--------|------------------|------------------------|
| Part 1 | 1 AMPULE | 10 mL |

Part 1 of 1

LIDOCAINE HYDROCHLORIDE

lidocaine hydrochloride anhydrous injection, solution

Product Information

 Item Code (Source)
 NDC:0409-4282

 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 | 20 mg in 1 mL | | |

| Inactive Ingredients | | | | |
|--------------------------------------|--------------|--|--|--|
| Ingredient Name | Strength | | | |
| Sodium Chloride (UNII: 451W47IQ8X) | 6 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:0409-4282-02 | 10 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 | OEZ | 02/20/2012 | | | |
| | | | | | |

Labeler - Centurion Medical Products (017246562)

| 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: 3/2012 Centurion Medical Products