DRESSING CHANGE TRAY-Centurion Medical Products

Dressing Change 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% of methylparaben added as preservative. May contain sodium hydroxide and/or cydrochloric adic for pH adjustment. The pH is 6.5 (5.0 to 7.0). Lidocaine is a local anesthetic of the amide type. Lidocaine Hydrochloride is a white powder freely soluable 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.

Dressing Change Tray Primary Label

CENTURION®

030712G

Example Dressing Change Tray

Reorder

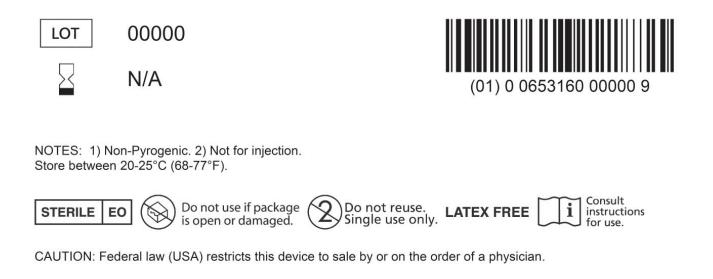


CONTENTS:

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

Example Only - Components & Title May Vary



CENTURION MEDICAL PRODUCTS CORP. | WILLIAMSTON | MI | 48895 USA | 800.248.4058 | www.centurionmp.com MM1

Lidocaine Label



MM1

DRESSING CHANGE TRAY

dressing change tray kit

Product Information

| Product Type | MEDICAL DEVICE | Item Code (Source |) N | HRIC:24840-1902 |) | |
|--|--|---------------------------------------|-----------------------------|-----------------------|------------------|--|
| | MEDICAL DEVICE | nem Code (Source | .) N | TIKIC.24040-1902 | <u> </u> | |
| | | | | | | |
| Packaging | | | | | | |
| # Item Code | Package Descriptio | Package Description Marketing Start D | | e Marketing End Date | | |
| 1 NHRIC:24840-1902-2 | 10 in 1 CASE | | | | | |
| 1 NHRIC:24840-1902-1 | 1 in 1 PACKAGE, COMBINATIO | N | | | | |
| | | | | | | |
| Quantity of Parts | | | | | | |
| Part # Pa | ckage Quantity | | Total Product Quantity | | | |
| Part 1 1 AMPULE | | 2 mL | | | | |
| | | | | | | |
| Part 1 of 1 | | | | | | |
| LIDOCAINE HY | DROCHLORIDE anhydrous injection, solution | 1 | | | | |
| Product Information | ı | | | | | |
| Item Code (Source) | NDC:0409-4713 | | | | | |
| Route of Administration | INFILTRATION | | | | | |
| | | | | | | |
| Active Ingredient/Ac | ctive Moiety | | | | | |
| | Ingredient Name | | Basis of | Strength | Strengt | |
| LIDO CAINE HYDRO CHLO (LIDO CAINE - UNII:98 PI200 | DRIDE ANHYDRO US (UNII: EC20 0987) | CNF7XFP) | LIDOCAINE HYDR ANHYDROUS | ROCHLORIDE | 10 mg in 1 mL | |
| | | | | | | |
| Inactive Ingredients | | | | | | |
| Inactive Ingredients | Ingredient Name | 2 | | Stren | ıgth | |
| SODIUM CHLORIDE (UNI | I: 451W47IQ8X) | 2 | | Stren 7 mg in 1 mL | ıgth | |
| SO DIUM CHLO RIDE (UNI WATER (UNII: 059QF0KO) | I: 451W47IQ8X) DR) | 2 | | | igth | |
| SODIUM CHLORIDE (UNI WATER (UNII: 059QF0KO) SODIUM HYDROXIDE (UM | I: 451W47IQ8X) DR) NII: 55X04QC32I) | 2 | | | ıgth | |
| SODIUM CHLORIDE (UNI WATER (UNII: 059QF0KO) SODIUM HYDROXIDE (UM | I: 451W47IQ8X) DR) NII: 55X04QC32I) | 2 | | | ngth | |
| SO DIUM CHLO RIDE (UNI WATER (UNII: 059QF0KO(SO DIUM HYDRO XIDE (UN HYDRO CHLO RIC ACID (U Packaging | I: 451W47IQ8X) DR) NII: 55X04QC32I) JNII: QTT17582CB) | | Start Date | 7 mg in 1 mL | | |
| Inactive Ingredients SODIUM CHLORIDE (UNI WATER (UNII: 059QF0KO) SODIUM HYDROXIDE (UN HYDROCHLORIC ACID (U Packaging # Item Code | E: 451W47IQ8X) DR) NII: 55X04QC32I) JNII: QTT17582CB) Package Description | 2 Marketing | Start Date | | | |
| SO DIUM CHLO RIDE (UNI WATER (UNII: 059QF0KO) SO DIUM HYDRO XIDE (UN HYDRO CHLO RIC ACID (U Packaging | I: 451W47IQ8X) DR) NII: 55X04QC32I) JNII: QTT17582CB) | | Start Date | 7 mg in 1 mL | - | |
| SO DIUM CHLO RIDE (UNI WATER (UNII: 059QF0KO) SO DIUM HYDRO XIDE (UN HYDRO CHLORIC ACID (U Packaging # Item Code | E: 451W47IQ8X) DR VII: 55X04QC32I) JNII: QTT17582CB) Package Description 2 mL in 1 AMPULE | | Start Date | 7 mg in 1 mL | | |

| ANDA | ANDA080408 | 03/30/2010 | | | |
|----------------------------------|--|--|--------------------|--|--|
| | | | | | |
| | | | | | |
| Marketing Information | | | | | |
| | | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | | |
| Marketing Category exempt device | Application Number or Monograph Citation OKV | Marketing Start Date 0 1/0 1/20 12 | Marketing End Date | | |

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