#### GENERAL SURGERY PROCEDURE KIT- general surgery tray (kit) Centurion Medical Products

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**General Surgery 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% 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 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.

#### Lidocaine Label



# **CENTURION®**

032312G

# Example General Surgery Tray

Reorder XXXXXXXX

CONTENTS:

1 STERILE EXAMPLE GENERAL SURGERY TRAY

1 STERILE LIDOCAINE HCI SOLUTION

## **Example Only - Components & Title May Vary**

LOT

000000000



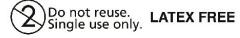
N/A



(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

#### **GENERAL SURGERY PROCEDURE KIT**

general surgery tray (kit) kit

#### **Product Information**

Product Type MEDICAL DEVICE Item Code (Source) NHRIC:24840-1508

| F | Packaging          |                             |                      |                    |  |  |
|---|--------------------|-----------------------------|----------------------|--------------------|--|--|
| # | Item Code          | Package Description         | Marketing Start Date | Marketing End Date |  |  |
| 1 | NHRIC:24840-1508-2 | 10 in 1 CASE                |                      |                    |  |  |
| 1 | NHRIC:24840-1508-1 | 1 in 1 PACKAGE, COMBINATION |                      |                    |  |  |

| Quan   | Quantity of Parts                         |       |  |  |
|--------|-------------------------------------------|-------|--|--|
| Part # | # Package Quantity Total Product Quantity |       |  |  |
| Part 1 | 1 VIAL, MULTI-DOSE                        | 20 mL |  |  |

#### Part 1 of 1

### LIDOCAINE HYDROCHLORIDE

lidocaine hydrochloride anhydrous injection, solution

| Product Information     |               |  |
|-------------------------|---------------|--|
| Item Code (Source)      | NDC:0409-4276 |  |
| 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 98 7) | LIDOCAINE HYDROCHLORIDE<br>ANHYDROUS | 10 mg<br>in 1 mL |  |  |

| Inactive Ingredients                   |              |  |  |  |
|----------------------------------------|--------------|--|--|--|
| Ingredient Name                        | Strength     |  |  |  |
| SODIUM CHLORIDE (UNII: 451W47IQ8X)     | 7 mg in 1 mL |  |  |  |
| WATER (UNII: 059QF0KO0R)               |              |  |  |  |
| SO DIUM HYDRO XIDE (UNII: 55X0 4QC32I) |              |  |  |  |
| HYDRO CHLORIC ACID (UNII: QTT17582CB)  |              |  |  |  |
| METHYLPARABEN (UNII: A2I8 C7HI9T)      | 1 mg in 1 mL |  |  |  |

| Packaging          |                             |                      |                    |  |
|--------------------|-----------------------------|----------------------|--------------------|--|
| # Item Code        | Package Description         | Marketing Start Date | Marketing End Date |  |
| 1 NDC:0409-4276-01 | 20 mL in 1 VIAL, MULTI-DOSE |                      |                    |  |
|                    |                             |                      |                    |  |

| Marketing Information |                                          |                      |                    |  |  |  |
|-----------------------|------------------------------------------|----------------------|--------------------|--|--|--|
| Marketing Category    | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |  |  |  |
| ANDA ANDA088299       |                                          | 03/30/2010           |                    |  |  |  |
|                       |                                          |                      |                    |  |  |  |
|                       |                                          |                      |                    |  |  |  |
| Marketing Information |                                          |                      |                    |  |  |  |
| Marketing Category    | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |  |  |  |
| exempt device         | LRO                                      | 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, Inc  |         | 093132819 | manufacture         |  |

Revised: 8/2012 Centurion Medical Products