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

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**General Surgery 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.

#### General Surgery Kit - Primary Label

MM1

# **CENTURION®**

030712G

## **Example General Surgery Tray**

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<sup>[1]</sup>
- 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

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

#### **Product Information**

**Product Type** MEDICAL DEVICE **Item Code (Source)** NHRIC:24840-1504

| Packaging   |           |                             |                      |                    |
|-------------|-----------|-----------------------------|----------------------|--------------------|
| # Ite       | n Code    | Package Description         | Marketing Start Date | Marketing End Date |
| 1 NHRIC:248 | 40-1504-2 | 10 in 1 CASE                |                      |                    |
| 1 NHRIC:248 | 40-1504-1 | 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<br>ANHYDROUS | 20 mg<br>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         | LRO                                      | 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