

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

General Surgery Kit

DESCRIPTION

This preparation is designed for parenteral use only after addition of drugs that require dilution or must be dissolved in an aqueous vehicle prior to injection. Bacteriostatic 0.9% sodium chloride injection, USP is a sterile, nonpyrogenic, isotonic solution of sodium chloride injection in water for injection. Each milliliter (mL) contains sodium chloride 9 mg and 0.9% benzyl alcohol added as bacteriostatic preservative. May contain hydrochloric acid for pH adjustment. It is supplied in a multiple dose container from which repeated withdrawals may be made to dilute or dissolve drugs for medication. The pH is 5.0 (4.5 to 7.0). Sodium chloride, USP is chemically designated as NaCl, a white crystalline powder freely soluble in water. The semi-rigid vial 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

General Surgery Kit Primary Label

CENTURION®

032312G

**Example General
Surgery Tray**

Reorder

XXXXXXXXXX

CONTENTS:

1 STERILE EXAMPLE GENERAL SURGERY TRAY

1 STERILE SODIUM CHLORIDE SOLUTION

Example Only - Components & Title May Vary

LOT 0000000000



N/A



(01) 1 0653160 00000 6

NOTES:

Store between 20-25°C (68-77°F).



Do not reuse.
Single use only.

LATEX FREE



Consult
instructions
for use.

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

Sodium Chloride Label

30 mL Multiple-dose
LifeShield® Vial

BACTERIOSTATIC
0.9% SODIUM Rx only
CHLORIDE Injection, USP

HOSPIRA, INC., LAKE FOREST, IL 60045 USA

NDC 0409-1966-14
NOT FOR INHALATION

WARNING: NOT FOR USE IN NEWBORNS.

FOR DRUG DILUENT USE ONLY.
Each mL contains sodium chloride 9 mg and
benzyl alcohol 9 mg added. Sterile,
nonpyrogenic. Cleanse stopper with antiseptic.
RL-0355 (7/04)



MM1

| GENERAL SURGERY KIT | | | | |
|--------------------------------|--------------------|-----------------------------|----------------------|--------------------|
| general surgery tray (kit) kit | | | | |
| Product Information | | | | |
| Product Type | MEDICAL DEVICE | Item Code (Source) | NHRIC:24840-1531 | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NHRIC:24840-1531-2 | 10 in 1 CASE | | |
| 1 | NHRIC:24840-1531-1 | 1 in 1 PACKAGE, COMBINATION | | |
| Quantity of Parts | | | | |
| Part # | Package Quantity | Total Product Quantity | | |
| Part 1 | 1 VIAL, MULTI-DOSE | 30 mL | | |
| Part 1 of 1 | | | | |
| SODIUM CHLORIDE | | | | |
| sodium chloride injection | | | | |
| Product Information | | | | |
| Item Code (Source) | NDC:0409-1966 | | | |
| Route of Administration | INTRAVENOUS | | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|--------------|
| SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:L4M0NH37, CHLORIDE ION - UNII:Q32ZN48698) | SODIUM CHLORIDE | 9 mg in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|--------------|
| BENZYL ALCOHOL (UNII: LKG8494WBH) | 9 mg in 1 mL |
| WATER (UNII: 059QF0K00R) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|-----------------------------|----------------------|--------------------|
| 1 | NDC:0409-1966-14 | 30 mL in 1 VIAL, MULTI-DOSE | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| NDA | NDA018800 | 08/19/2011 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| exempt device | LRO | 01/01/2012 | |

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 | | 626660810 | manufacture, repack |

Establishment

| Name | Address | ID/FEI | Business Operations |
|---------------|---------|-----------|---------------------|
| Hospira, Inc. | | 093132819 | manufacture |