

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 injections, 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 a 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 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 a vapor barrier to maintain the proper drug concentration.

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

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:24840-1530	
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:24840-1530-2	10 in 1 CASE		
1	NHRIC:24840-1530-1	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:0409-1966-07	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