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 prio to injection. Bacteriostatic 0.9% sodium chloride injections, USP is a sterile, nonpyrogenic, isotonic solution of sodium chloride injection in water for injection. Each mililiter (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 withdrawls 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 soluable in water. The semi-ridgid vial is fabricated from a specially formulated plyolefin. 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 novapor barrier to maintain the proper drug concentration.

General Surgery Kit Primary Label



032312G

Example General Surgery Tray

Reorder XXXXXXXX

CONTENTS:

1 STERILE EXAMPLE GENERAL SURGERY TRAY

1 STERILE SODIUM CHLORIDE SOLUTION

Example Only - Components & Title May Vary



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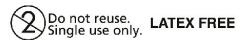


N/A



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

MM1

30 mL Multiple-dose LifeShield® Vial

BACTERIOSTATIC 0.9% SODIUM Boonly 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

ı				
	Part #	Package Quantity	Total Product Quantity	
	Part 1	1 VIAL, MULTI-DO SE	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:LYR4M0NH37, 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: 059QF0KO0R)				

Pa	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	NDA0 18 8 0 0	08/19/2011		

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		626660810	manufacture, repack

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

Revised: 5/2012 Centurion Medical Products