

CARDIOVASCULAR PROCEDURE KIT - Centurion Medical Products

Cardiovascular Procedure Kit

DESCRIPTION

This preparation is designed solely for parenteral use only after addition of drugs that require dilution or must be dissolved in an aqueous vehicle prior to injection. 0.9% Sodium chloride injection, USP is a sterile, nonpyrogenic, isotonic solution of sodium chloride and water for injection. It contains no bacteriostat, antimicrobial agent or added buffer and is supplied only in single dose containers to dilute or dissolve drugs for injection. The solution may contain hydrochloric acid and/or sodium hydroxide for pH adjustment. pH is 5.3 (4.5 to 7.0). Sodium Chloride, USP is chemically designated NaCl, a white crystalline compound freely soluble in water.



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CENTURION®

032312G

Example Cardiovascular Kit

Reorder

XXXXXXXXXX

CONTENTS:

1 STERILE EXAMPLE CARDIOVASCULAR KIT

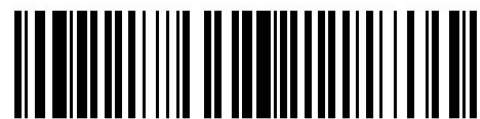
1 STERILE SODIUM CHLORIDE SOLUTION

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.

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CARDIOVASCULAR PROCEDURE KIT

cardiovascular procedure kit kit

Product Information

Product Type	MEDICAL DEVICE	Item Code (Source)	NHRIC:24840-1134
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:24840-1134-2	10 in 1 CASE		
1	NHRIC:24840-1134-1	1 in 1 PACKAGE, COMBINATION		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 VIAL, SINGLE-DOSE	20 mL

Part 1 of 1

SODIUM CHLORIDE

sodium chloride injection, solution

Product Information

Item Code (Source)	NDC:0409-4888
Route of Administration	INTRAVENOUS, INTRAMUSCULAR

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:L4YR4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	9 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0409-4888-20	20 mL in 1 VIAL, SINGLE-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA018803	09/08/2011	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
exempt device	OEZ	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		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: 9/2012

Centurion Medical Products