

**SODIUM CHLORIDE SOLUTION- sodium chloride  
PharmaCaribe**

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**Sodium Chloride Solution USP 7%**

**DESCRIPTION**

**Sodium Chloride Inhalation Solution USP 7% 4 mL**

**For Respiratory Therapy**

**Not for parenteral administration.**

***4 mL, 60 Vials Sterile Unit-Dose Vial***

**Discard any unused portion of the contents of this single-use vial as well as any unused solution remaining in the nebulizer cup.**

Internal contents sterile. External surface of vial not sterile.

**INDICATIONS AND USAGE**

The contents of these vials are used in conjunction with a nebulizer for the induction of sputum production where sputum production is indicated.

**INSTRUCTIONS FOR USE SECTION**

Hold vial gently twist and pull off top. Invert and squeeze to dispense prescribed volume into the nebulizer cup.

**How Supplied**

Single-use plastic vials containing 4ml solution in cartons of 60 vials.

**WARNINGS**

Not for injection or parenteral administration.

**STORAGE**

Store at room temperature 15° to 30° C (50° to 86°F). Avoid excessive heat and protect from freezing.

**Sodium Chloride Inhalation Solution USP 7% 4 mL**

**PRODUCT CODE 50190-141-23**

**Rx Only**

Manufactured by: **Asept Pak, Inc.** , Malone, NY 12953

Exclusively Distributed by: **Cystic Fibrosis Services, Inc.** , Bethesda, MD 20814

NDC 50190-141-23  
60 X 4ml Unit Dose Vials



### Sodium Chloride Solution USP 7%

Sterile, Preservative-free, Non-pyrogenic

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Sodium Chloride Solution 7%  
Each single-use vial contains 4ml sterile, preservative-free, non-pyrogenic Sodium Chloride Solution 7% for inhalation.

**INDICATIONS:** The contents of these vials are used in conjunction with a nebulizer for the induction of sputum production where sputum production is indicated.

**WARNING:** Not for injection or parenteral administration.

**DIRECTIONS FOR USE:** Hold vial gently twist and pull off top. Invert and squeeze to dispense prescribed volume into the nebulizer cup. Discard any unused solution of this single-use vial and any unused solution remaining in the nebulizer cup.

**HOW SUPPLIED:** Single-use plastic vials containing 4ml solution in boxes of 60 vials.

NDC# 50190-141-23

**STORAGE:** Store at room temperature 15° to 30° C (50° to 86 °F). Avoid excessive heat and protect from freezing.

**CAUTION:** Rx only

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60 X 4ml Unit Dose Vials

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NOT FOR INJECTION

LOT:

EXP:

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## SODIUM CHLORIDE SOLUTION

nebulizer (direct patient interface)

### Product Information

<b>Product Type</b>	MEDICAL DEVICE	<b>Item Code (Source)</b>	NHRIC:50 190-141
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### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8 X) (CHLORIDE ION - UNII:Q32ZN48698, SODIUM CATION - UNII:L4YR4M0NH37)	SODIUM CHLORIDE	280 mg in 4 mL

### Product Characteristics

<b>number of times usable</b>	1
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:50 190-141-23	60 in 1 BOX		
1		4 mL in 1 VIAL		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
exempt device	CAF	08/17/2010	

**Labeler** - PharmaCaribe (011702541)

**Registrant** - PharmaCaribe (011702541)

## Establishment

Name	Address	ID/FEI	Business Operations
PharmaCaribe		011702541	label

Revised: 11/2013

PharmaCaribe