#### PULMOSAL- sodium chloride PharmaCaribe

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Pulmosal 7% (pH+)

#### **DESCRIPTION**

Pulmosal 7% (pH+) 4 mL Sodium Chloride Inhalation Solution 7%, Sterile, Preservative-free, Non-pyrogenic, pH 7.4

Each Single-use vial contains 4ml sterile, preservative-free, non-pyrogenic Sodium Chloride Solution 7% for inhalation, pH 7.4

#### FOR INHALATION ONLY

NOT FOR INJECTION.

Patent Pending RX Only

60 x 4 mL Unit-Dose Vial

NOT SUBSTITUTABLE with USP 7% Sodium Chloride

#### 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. 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 cartons of 60 vials. **NDC:50190-740-60** 

#### 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.

Pulmosal 7% (pH+) 4 mL PRODUCT CODE 50190-740-60 Rx Only Manufactured by: Asept Pak, Inc., Malone, NY 12953

Manufactured For: PharmaCaribe, LLC, Punta Gorda, FL 33950



#### **PULMOSAL**

nebulizer (direct patient interface)

#### **Product Information**

Product Type MEDICAL DEVICE Item Code (Source) NHRIC:50190-740

Active Ingredient/Active Moiety				
Ingredient Name		Strength		
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8 X) (CHLORIDE ION - UNII:Q32ZN48698, SODIUM CATION - UNII:LYR4M0 NH37)	SODIUM CHLORIDE	280 mg in 4 mL		

# Product Characteristics number of times usable 1

Packaging					
# Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date		
1 NHRIC:50190-740-60	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		0 1170 2541	label

Revised: 11/2013 PharmaCaribe