

**NEBUSAL- sodium chloride
PharmaCaribe**

Nebusal 6%

DESCRIPTION

Sodium Chloride Inhalation Solution USP 6% 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 6% 4 mL

PRODUCT CODE 50190-523-22

Rx Only

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

Distributed by: **PharmaCaribe LLC.** , Punta Gorda, FL 33950

NDC 50190-523-22
60 X 4ml Unit Dose Vials



NEBUSAL™ 6%

Sodium Chloride Solution USP 6%

NEBUSAL™ 6%

Sodium Chloride Inhalation Solution USP 6%

NEBUSAL™ Sodium Chloride Solution 6%
Each single-use vial contains 4ml sterile, preservative free, non-pyrogenic Sodium Chloride Solution 6% 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 cartons of 60 vials.

NDC# 50190-523-22

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

CAUTION: Rx only

Manufactured by: Asept Pak, Inc., Malone, NY 12953
Distributed by: PharmaCaribe, LLC, Punta Gorda, FL 33950



60 X 4ml Unit Dose Vials

NEBUSAL™ 6%

Sodium Chloride Solution USP 6%

Sterile, Preservative-free, Non-pyrogenic

FOR INHALATION ONLY
NOT FOR INJECTION

LOT:

EXP:

NDC 50190-523-22
60 X 4ml Unit Dose Vials



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NEBUSAL

nebulizer (direct patient interface)

Product Information

| | | | |
|---------------------|----------------|---------------------------|------------------|
| Product Type | MEDICAL DEVICE | Item Code (Source) | NHRIC:50 190-523 |
|---------------------|----------------|---------------------------|------------------|

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------------|
| SODIUM CHLORIDE (UNII: 451W47IQ8 X) (CHLORIDE ION - UNII:Q32ZN48698) | SODIUM CHLORIDE | 240 mg in 4 mL |

Product Characteristics

| | |
|-------------------------------|---|
| number of times usable | 1 |
|-------------------------------|---|

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---------------------|---------------------|----------------------|--------------------|
| 1 | NHRIC:50 190-523-22 | 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 | 08/17/20 10 | |

Labeler - PharmaCaribe (011702541)

Registrant - PharmaCaribe (011702541)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------|---------|-----------|---------------------|
| PharmaCaribe | | 011702541 | label |

Revised: 9/2013

PharmaCaribe