

SODIUM CHLORIDE- sodium chloride
Nephron Pharmaceuticals Corporation

Sodium Chloride Inhalation Solution, USP 0.9%

Sodium Chloride Inhalation Solution, USP 0.9% 3 mL

NDC 0487-9301-33

Sodium Chloride

Inhalation Solution, USP 0.9%

Sterile, non-pyrogenic, preservative-free
single-use vials for respiratory therapy.

No bacteriostatic agent or other
preservative added.

**MADE
IN THE
USA**

For Respiratory Therapy

Not for parenteral administration.

nephron
pharmaceuticals
corporation
Orlando, FL 32811

30 × 3 mL Sterile Unit-Dose Vials, each in a foil pouch.

INDICATIONS: This sterile, single-use device is intended to be used as an accessory to medicinal nonventilatory nebulizers for respiratory therapy or for tracheal irrigation or lavage therapy.

This device is not intended for parenteral use or for preparations intended for parenteral use.

WARNING: Not for injection or in preparations to be used for injection.

DIRECTIONS FOR USE: To verify container integrity, squeeze the vial before use. Twist cap completely off vial, invert and squeeze prescribed volume.

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

HOW SUPPLIED: Sodium Chloride Inhalation Solution, USP 0.9% is supplied in single-use plastic vials in the following configurations:

NDC 0487-9301-03 3 mL, 100 vials per carton

NDC 0487-9301-33 3 mL, 30 vials per carton / 1 vial per foil pouch

NDC 0487-9301-02 3 mL, 30 vials per carton / 1 vial per foil pouch / robot ready

NDC 0487-9302-01 5 mL, 100 vials per carton

NDC 0487-9315-30 15 mL, 30 vials per carton

Internal contents sterile. External surface of vial not sterile.

STORAGE: Store at controlled room temperature 15° to 30°C (59° to 86°F).

Rx Only

Please Recycle

IC 426
Rev. 09-23-14

NDC 0487-9301-33

Sodium Chloride Inhalation Solution, USP 0.9%

Sterile, non-pyrogenic, preservative-free single-use vials for respiratory therapy.

No bacteriostatic agent or other preservative added.



For Respiratory Therapy
Not for parenteral administration.

30 x 3 mL Sterile Unit-Dose Vials, each in a foil pouch.

IC-498
Rev. 06-23-14



Rx Only

STORAGE: Store at controlled room temperature 15° to 30°C (59° to 86°F).

Internal contents sterile. External surface of vial not sterile.

NDC 0487-9315-30 15 mL, 30 vials per carton

NDC 0487-9302-01 5 mL, 100 vials per carton

NDC 0487-9301-02 3 mL, 30 vials per carton / 1 vial per foil pouch / robot ready

NDC 0487-9301-33 3 mL, 30 vials per carton / 1 vial per foil pouch

NDC 0487-9301-03 3 mL, 100 vials per carton

vials in the following configurations:

HOW SUPPLIED: Sodium Chloride Inhalation Solution, USP 0.9% is supplied in single-use plastic

Discard any unused portion of the contents of this single-use vial as well as any unused

cup.

INDICATIONS: This sterile, single-use device is intended to be used as an accessory to medicinal nebulizers for respiratory therapy or for tracheal irrigation or lavage therapy.
WARNING: Not intended for parenteral use or for preparations intended for parenteral use. This device is not intended for injection or in preparations to be used for injection.
DIRECTIONS FOR USE: To verify container integrity, squeeze the vial before use. Twist cap completely off vial. Invert and squeeze prescribed volume.

NDC 0487-9301-33

Sodium Chloride Inhalation Solution, USP 0.9%

Sterile, non-pyrogenic, preservative-free single-use vials for respiratory therapy.

No bacteriostatic agent or other preservative added.



Please Recycle

For Customer Service,
Call: 1-800-443-4313

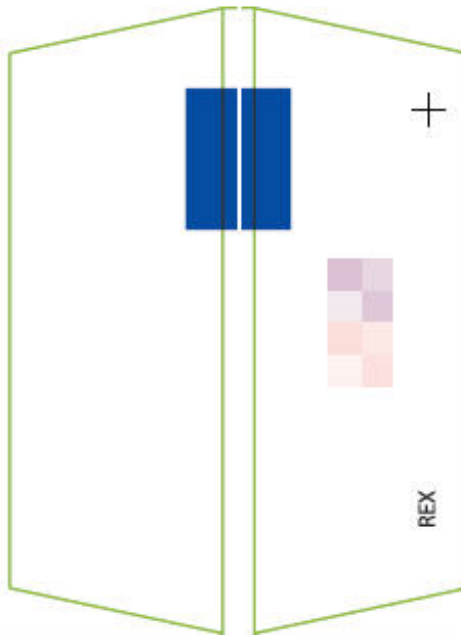
Email: CustomerService@nephronpharm.com

For Respiratory Therapy

Not for parenteral administration.



30 x 3 mL Sterile Unit-Dose Vials, each in a foil pouch.



NDC 0487-

Soc
Inha

Sterile, no
single-use
No bacteri
added.

For Resp
Not for pe
30 x 3 mL

on
pharmaceuticals
nephron

%

NDC 0487-9301-33

Sodium Chloride Inhalation Solution, USP 0.9%

Sterile, non-pyrogenic, preservative-free
single-use vials for respiratory therapy.
No bacteriostatic agent or other preservative
added.



For Respiratory Therapy
Not for parenteral administration.
30 x 3 mL Sterile Unit-Dose Vials, each in a foil pouch.

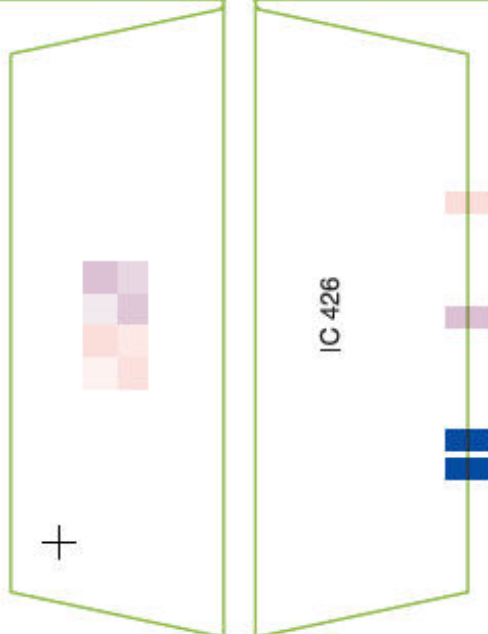
Respiratory Therapy
Not for parenteral administration.
Sterile Unit-Dose Vials, each in a foil pouch.



Sterile, non-pyrogenic, preservative-free
single-use vials for respiratory therapy.
No bacteriostatic agent or other preservative
added.

-9301-33

Sodium Chloride Inhalation Solution, USP 0.9%



Sodium Chloride Inhalation Solution, USP 0.9% 5 mL

NDC 0487-9302-01

Sodium Chloride

Inhalation Solution, USP 0.9%

Sterile, non-pyrogenic, preservative-free
single-use vials for respiratory therapy.

No bacteriostatic agent or other preservative
added.

For Respiratory Therapy

Not for parenteral administration.

100 x 5 mL Sterile Unit-Dose Vials

Manufactured By:

nephron

pharmaceuticals
corporation
Orlando, FL 32811

INDICATIONS: This sterile, single-use device is intended to be used as an accessory to medicinal nonventilatory nebulizers for respiratory therapy or for tracheal irrigation or lavage therapy.

This device is not intended for parenteral use or for preparations intended for parenteral use.

WARNING: Not for injection or in preparations to be used for injection.

DIRECTIONS FOR USE: To verify container integrity, squeeze the vial before use. Twist cap completely off vial, invert and squeeze prescribed volume.

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

HOW SUPPLIED: Sodium Chloride Inhalation Solution, USP 0.9% is supplied in single-use plastic vials in the following configurations:

NDC 0487-9301-03 3 mL, 100 vials per carton

NDC 0487-9301-33 3 mL, 30 vials per carton / 1 vial per foil pouch

NDC 0487-9301-02 3 mL, 30 vials per carton / 1 vial per foil pouch / robot ready

NDC 0487-9302-01 5 mL, 100 vials per carton

NDC 0487-9315-30 15 mL, 30 vials per carton

Internal contents sterile. External surface of vial not sterile.

STORAGE: Store at controlled room temperature 15° to 30°C (59° to 86°F).

Rx Only

Please Recycle

IC 440

Rev. 09-23-14

NDC 0487-9302-01

Sodium Chloride

Inhalation Solution, USP 0.9%

Sterile, non-pyrogenic, preservative-free single-use vials for respiratory therapy.

No bacteriostatic agent or other preservative added.

For Respiratory Therapy
Not for parenteral administration.
100 x 5 mL Sterile Unit-Dose Vials

Manufactured By:
nephron
pharmaceuticals
corporation
Orlando, FL 32811



NDC 0487-9302-01

Sodium Chloride

Inhalation Solution, USP 0.9%

Sterile, non-pyrogenic, preservative-free single-use vials for respiratory therapy.

No bacteriostatic agent or other preservative added.

For Respiratory Therapy
Not for parenteral administration.
100 x 5 mL Sterile Unit-Dose Vials

REX

100 x 5 mL Sterile Unit-Dose Vials
Not for parenteral administration.
For Respiratory Therapy



Please Recycle

For Customer Service,

Call 1-800-443-513

Email: customerservice@nephronpharm.com



Sterile, non-pyrogenic, preservative-free single-use vials for respiratory therapy.
No bacteriostatic agent or other preservative added.

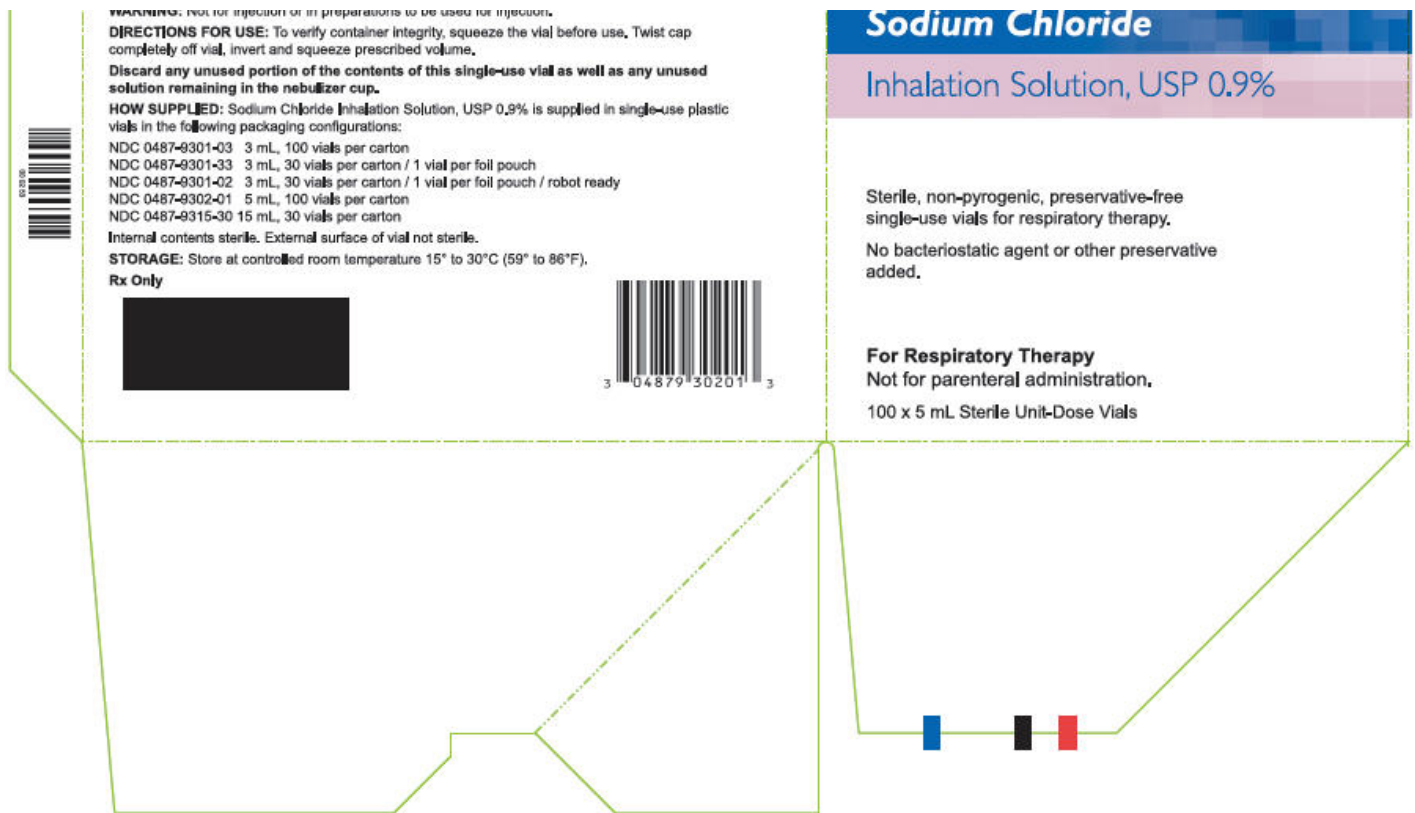
Sodium Chloride
Inhalation Solution, USP 0.9%

NDC 0487-9302-01

INDICATIONS: This sterile, single-use device is intended to be used as an accessory to medicinal nonventilatory nebulizers for respiratory therapy or for tracheal irrigation or lavage therapy. This device is not intended for parenteral use or for preparations intended for parenteral use.
WARNING: Not for injection or in preparations to be used for injection.

IC 440
Rev. 09/2014

NDC 0487-9302-01



Sodium Chloride Inhalation Solution, USP 0.9% 15 mL

NDC 0487-9315-30

Sodium Chloride

Inhalation Solution, USP 0.9%

Sterile, non-pyrogenic, preservative-free single-use vials for respiratory therapy.

No bacteriostatic agent or other preservative added.

For Respiratory Therapy

Not for parenteral administration.

30 × 15 mL Sterile Unit-Dose Vials

Manufactured By:

nephron
pharmaceuticals
corporation
Orlando, FL 32811

**MADE
IN THE
USA**

INDICATIONS: This sterile, single-use device is intended to be used as an accessory to medicinal nonventilatory nebulizers for respiratory therapy or for tracheal irrigation or lavage therapy.

This device is not intended for parenteral use or for preparations intended for parenteral use.

WARNING: Not for injection or in preparations to be used for injection.

DIRECTIONS FOR USE: To verify container integrity, squeeze the vial before use. Twist cap completely off vial, invert and squeeze prescribed volume.

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

HOW SUPPLIED: Sodium Chloride Inhalation Solution, USP 0.9% is supplied in single-use plastic vials in the following packaging configurations:

NDC 0487-9301-03 3 mL, 100 vials per carton

NDC 0487-9301-33 3 mL, 30 vials per carton / 1 vial per foil pouch

NDC 0487-9301-02 3 mL, 30 vials per carton / 1 vial per foil pouch / robot ready

NDC 0487-9302-01 5 mL, 100 vials per carton

NDC 0487-9315-30 15 mL, 30 vials per carton

STORAGE: Store at controlled room temperature 15° to 30°C (59° to 86°F).

Internal contents sterile. External surface of vial not sterile.

Rx Only

IC 446

Rev. 08-27-14

NDC 0487-9315-30

Sodium Chloride

Inhalation Solution, USP 0.9%

Sterile, non-pyrogenic, preservative-free single-use vials for respiratory therapy.

No bacteriostatic agent or other preservative added.

For Respiratory Therapy
Not for parenteral administration.

30 x 15 mL Sterile Unit-Dose Vials

Manufactured By:
nephron
pharmaceuticals
corporation
Orlando, FL 32811



NDC 0487-9315-30

Sodium Chloride

Inhalation Solution, USP 0.9%

Sterile, non-pyrogenic, preservative-free single-use vials for respiratory therapy.

No bacteriostatic agent or other preservative added.

For Respiratory Therapy
Not for parenteral administration.

30 x 15 mL Sterile Unit-Dose Vials

REX

NDC 0487-9315-30

Sodium Chloride

Inhalation Solution, USP 0.9%

Sterile, non-pyrogenic, preservative-free single-use vials for respiratory therapy. No bacteriostatic agent or other preservative added.

For Respiratory Therapy
Not for parenteral administration.

30 x 15 mL Sterile Unit-Dose Vials

Please Recycle

For Customer Service, Call: 1-800-443-4313
Email: CustomerService@nephronpharm.com

INDICATIONS: This sterile, single-use device is intended to be used as an accessory to medicinal nonventilatory nebulizers for respiratory therapy or for tracheal irrigation or lavage therapy. This device is not intended for parenteral use or for preparations intended for parenteral use.


WARNING: Not for injection or in preparations to be used for injection.

DIRECTIONS FOR USE: To verify container integrity, squeeze the vial before use. Twist cap completely off vial, invert and squeeze prescribed volume.

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

HOW SUPPLIED: Sodium Chloride Inhalation Solution, USP 0.9% is supplied in single-use plastic vials in the following packaging configurations:
 NDC 0487-9301-03 3 mL, 100 vials per carton
 NDC 0487-9301-33 3 mL, 30 vials per carton / 1 vial per foil pouch
 NDC 0487-9301-02 3 mL, 30 vials per carton / 1 vial per foil pouch / robot ready
 NDC 0487-9302-01 5 mL, 100 vials per carton
 NDC 0487-9315-30 15 mL, 30 vials per carton

STORAGE: Store at controlled room temperature 15° to 30°C (59° to 86°F).



IC 448
Rev 08-27-16

Internal contents sterile. External surface of vial not sterile. **Rx Only**

NDC 0487-9315-30

Sodium Chloride

Inhalation Solution, USP 0.9%

Sterile, non-pyrogenic, preservative-free single-use vials for respiratory therapy.

No bacteriostatic agent or other preservative added.

For Respiratory Therapy
 Not for parenteral administration.
 30 x 15 mL Sterile Unit-Dose Vials

SODIUM CHLORIDE

nebulizer (direct patient interface)

Product Information

| | | | |
|--------------------------------|--------------------------|---------------------------|-----------------|
| Product Type | MEDICAL DEVICE | Item Code (Source) | NHRIC:0487-9301 |
| Route of Administration | RESPIRATORY (INHALATION) | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|--------------|
| Sodium Chloride (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37) | Sodium Chloride | 9 mg in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--------------------------|----------|
| Water (UNII: 059QF0KO0R) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|--------------------|----------------------------|----------------------|--------------------|
| 1 | NHRIC:0487-9301-33 | 30 in 1 CARTON | | |
| 1 | | 1 in 1 POUCH | | |
| 1 | | 3 mL in 1 VIAL, SINGLE-USE | | |
| 2 | NHRIC:0487-9301-03 | 100 in 1 CARTON | | |

| | | | | |
|---|--------------------|----------------------------|--|--|
| 2 | | 3 mL in 1 VIAL, SINGLE-USE | | |
| 3 | NHRIC:0487-9301-02 | 1 in 1 BAG | | |
| 3 | | 1 in 1 POUCH | | |
| 3 | | 3 mL in 1 VIAL, SINGLE-USE | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| EXEMPT DEVICE | CAF | 06/25/2012 | |

SODIUM CHLORIDE

nebulizer (direct patient interface)

Product Information

| | | | |
|-------------------------|--------------------------|--------------------|-----------------|
| Product Type | MEDICAL DEVICE | Item Code (Source) | NHRIC:0487-9302 |
| Route of Administration | RESPIRATORY (INHALATION) | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|--------------|
| Sodium Chloride (UNII: 451W47IQ8X) (SODIUM CATION - UNII:L4YR4M0NH37) | Sodium Chloride | 9 mg in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--------------------------|----------|
| Water (UNII: 059QF0KO0R) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|--------------------|----------------------------|----------------------|--------------------|
| 1 | NHRIC:0487-9302-01 | 100 in 1 CARTON | | |
| 1 | | 5 mL in 1 VIAL, SINGLE-USE | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| EXEMPT DEVICE | CAF | 06/25/2012 | |

SODIUM CHLORIDE

nebulizer (direct patient interface)

Product Information

| | | | |
|--------------|----------------|--------------------|-----------------|
| Product Type | MEDICAL DEVICE | Item Code (Source) | NHRIC:0487-9315 |
|--------------|----------------|--------------------|-----------------|

| | | | | |
|--|---|-----------------------------|-----------------------------|---------------------------|
| Route of Administration | | RESPIRATORY (INHALATION) | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| Sodium Chloride (UNII: 451W47IQ8X) (SODIUM CATION - UNII:L4M0NH37) | | Sodium Chloride | 9 mg in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| WATER (UNII: 059QF0KO0R) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NHRIC:0487-9315-30 | 30 in 1 CARTON | | |
| 1 | | 15 mL in 1 VIAL, SINGLE-USE | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| EXEMPT DEVICE | CAF | 02/09/2015 | | |

Labeler - Nephron Pharmaceuticals Corporation (783905201)

| | | | |
|-------------------------------------|----------------|---------------|-----------------------------|
| Establishment | | | |
| Name | Address | ID/FEI | Business Operations |
| Nephron Pharmaceuticals Corporation | | 783905201 | MANUFACTURE, ANALYSIS, PACK |

Revised: 1/2015

Nephron Pharmaceuticals Corporation