

SODIUM CHLORIDE- sodium chloride
Mylan Pharmaceuticals Inc.

Sodium Chloride Inhalation Solution 3% 15 mL

PRODUCT CODE 0378-6997-89

Sodium Chloride
Inhalation Solution, USP
Sterile,
Preservative-free, Single-use Vials

3% 15 mL

For Respiratory Therapy

Not for parenteral administration.

15 mL, 50 Vials

Sterile

Unit-Dose Vial

Sodium Chloride Inhalation Solution, USP

3% 15 mL

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

INDICATIONS: Contents of these vials are for use in the induction of sputum production where specimen collection is indicated.

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: Single-use plastic vials containing 15 mL solutions supplied in cartons of 50 vials.

PRODUCT CODE 0378-6997-89 Sodium Chloride Inhalation Solution, USP 3%, 15 mL

PRODUCT CODE 0378-6998-89 Sodium Chloride Inhalation Solution, USP 10%, 15 mL

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

CAUTION: Federal law restricts this device to sale by or on the order of a Physician.

Manufactured for: **Mylan Pharmaceuticals Inc.**, Morgantown, WV 26505 Manufactured by: **The Ritedose Corporation**, Columbia, SC 26203

TRC:6997:50C:R3



Sodium Chloride Inhalation Solution 10% 15 mL

PRODUCT CODE 0378-6998-89

**Sodium Chloride
Inhalation Solution, USP**

**Sterile,
Preservative-free, Single-use Vials
10% 15 mL**

For Respiratory Therapy

Not for parenteral administration.

15 mL, 50 Vials

Sterile

Unit-Dose Vial

Sodium Chloride Inhalation Solution, USP

10% 15 mL

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

INDICATIONS: Contents of these vials are for use in the induction of sputum production where specimen collection is indicated.

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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: Single-use plastic vials containing 15 mL solutions supplied in cartons of 50 vials.

PRODUCT CODE 0378-6997-89 Sodium Chloride Inhalation Solution, USP 3%, 15 mL

PRODUCT CODE 0378-6998-89 Sodium Chloride Inhalation Solution, USP 10%, 15 mL

Internal contents sterile. External surface of vial not sterile.

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TRC:6998:50C:R3



SODIUM CHLORIDE

nebulizer (direct patient interface)

Product Information

Product Type	MEDICAL DEVICE	Item Code (Source)	NHRIC:0378-6997
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37)	SODIUM CHLORIDE	0.45 g in 15 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:0378-6997-89	50 in 1 CARTON		
1		15 mL in 1 VIAL; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Premarket Notification	K972778	10/15/2009	

SODIUM CHLORIDE

nebulizer (direct patient interface)

Product Information

Product Type	MEDICAL DEVICE	Item Code (Source)	NHRIC:0378-6998

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:L4M0NH37)	SODIUM CHLORIDE	1.5 g in 15 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:0378-6998-89	50 in 1 CARTON		
1		15 mL in 1 VIAL; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Premarket Notification	K972778	10/15/2009	

Labeler - Mylan Pharmaceuticals Inc. (059295980)

Revised: 10/2017

Mylan Pharmaceuticals Inc.