

SODIUM CHLORIDE- sodium chloride
Mylan Pharmaceuticals Inc.

Sodium Chloride Inhalation Solution 0.9% 3 mL

PRODUCT CODE 0378-6985-01

Sodium Chloride
Inhalation Solution, USP
0.9% 3 mL

For Respiratory Therapy

Not for Parenteral Administration.

100 x 3 mL
Sterile Unit-Dose Vials

Sodium Chloride Inhalation Solution, USP
0.9% 3 mL

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

INDICATIONS: Contents of these vials are for use in respiratory therapy and for tracheal irrigation or lavage.

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 3 mL or 5 mL solutions supplied in cartons of 100 vials and 15 mL solution supplied in cartons of 50 vials.

PRODUCT CODE 0378-6985-01 Sodium Chloride Inhalation Solution, USP 0.9%, 3 mL

PRODUCT CODE 0378-6986-01 Sodium Chloride Inhalation Solution, USP 0.9%, 5 mL

PRODUCT CODE 0378-6987-89 Sodium Chloride Inhalation Solution, USP 0.9%, 15 mL

Internal contents sterile. External surface of vial not sterile.

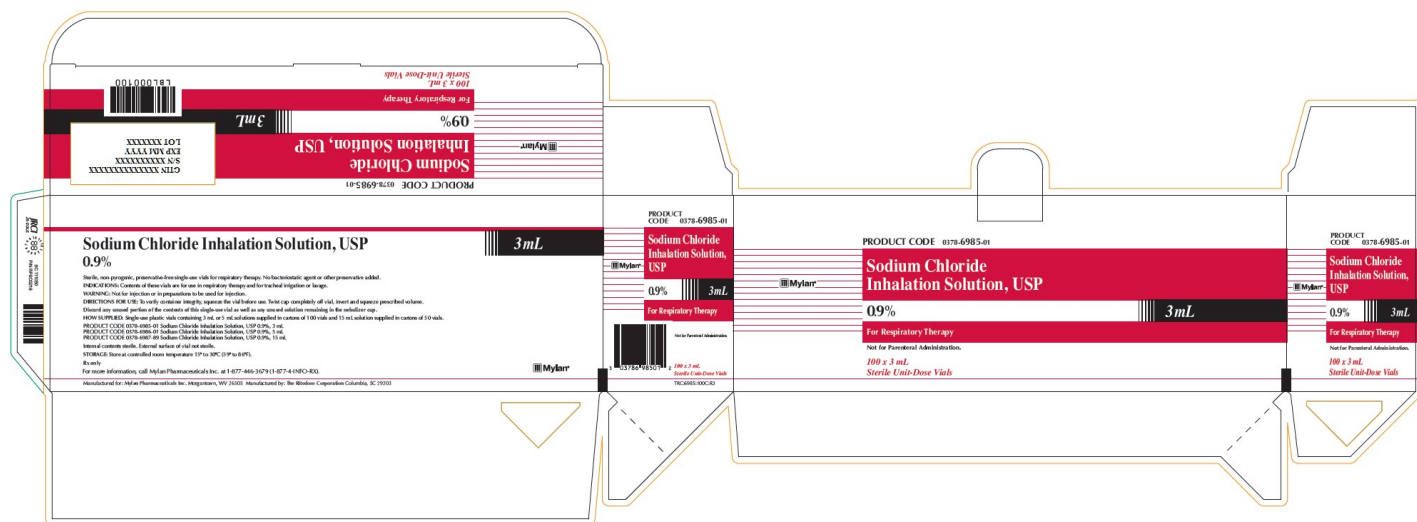
STORAGE: Store at controlled room temperature 15° to 30°C (59° to 86°F).

Rx only

For more information, call Mylan Pharmaceuticals Inc. at 1-877-446-3679 (1-877-4-INFO-RX).

Manufactured for: **Mylan Pharmaceuticals Inc.** Morgantown, WV 26505 Manufactured by: **The Ritedose Corporation** Columbia, SC 29203

TRC:6985:100C:R3



Sodium Chloride Inhalation Solution 0.9% 5 mL

PRODUCT CODE 0378-6986-01

**Sodium Chloride
Inhalation Solution, USP
0.9% 5 mL**

For Respiratory Therapy

Not for Parenteral Administration.

100 x 5 mL

Sterile Unit-Dose Vials

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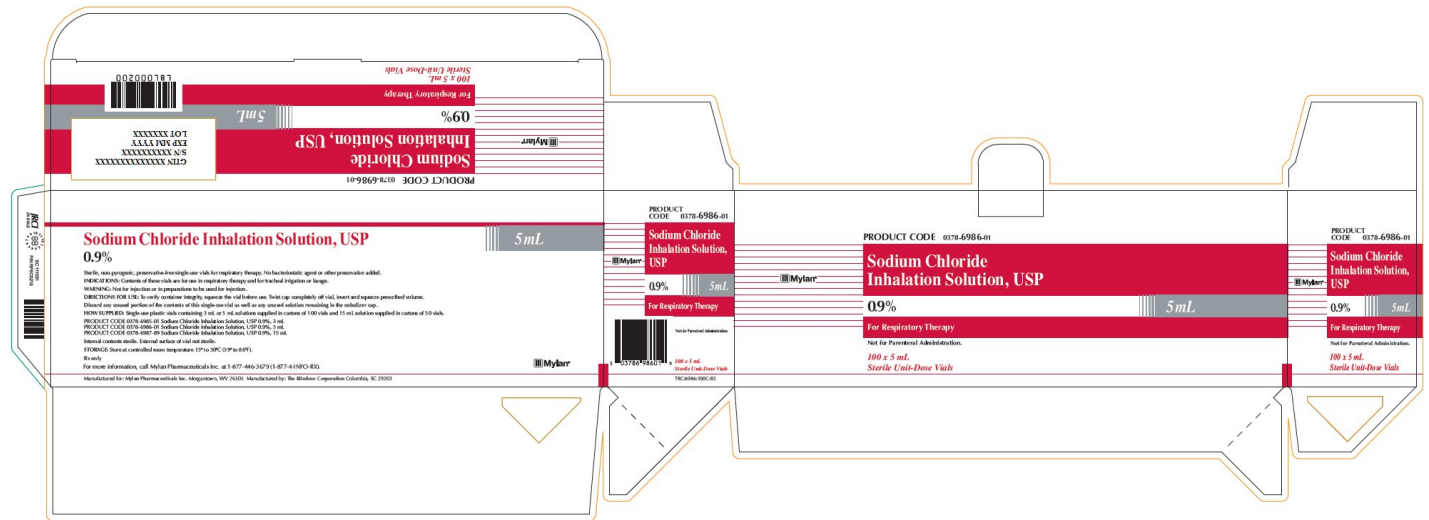
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TRC:6986:100C:R3



Sodium Chloride Inhalation Solution 0.9% 15 mL

PRODUCT CODE 0378-6987-89

**Sodium Chloride
Inhalation Solution, USP
0.9% 15 mL**

For Respiratory Therapy

Not for parenteral administration.

50 x 15 mL

Sterile Unit-Dose Vials

**Sodium Chloride Inhalation Solution, USP
0.9% 15 mL**

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

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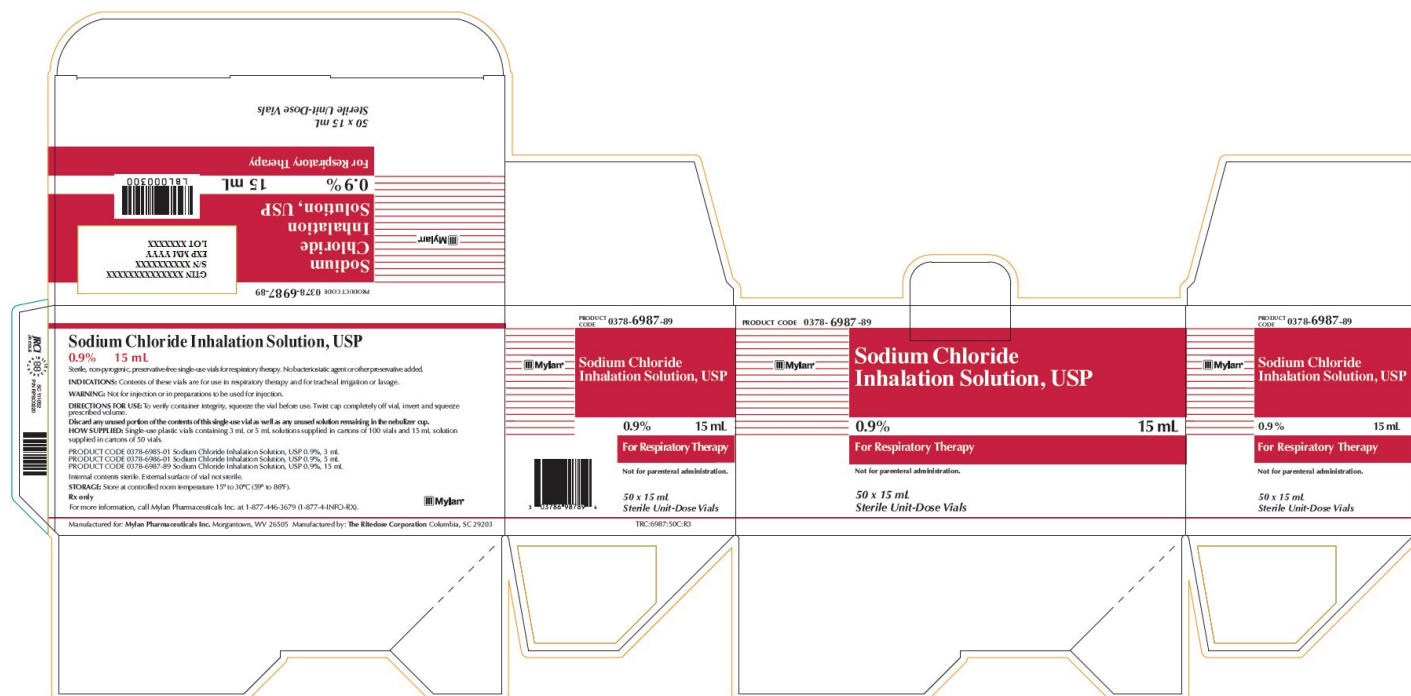
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Manufactured for: **Mylan Pharmaceuticals Inc.**, Morgantown, WV 26505 Manufactured by: **The Ritedose Corporation** Columbia, SC 29203

TRC:6987:50C:R3



SODIUM CHLORIDE

nebulizer (direct patient interface)

Product Information

Product Type	MEDICAL DEVICE	Item Code (Source)	NHRIC:0378-6985
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8 X) (SODIUM CATION - UNII:LYR4M0NH37)	SODIUM CHLORIDE	0.027 g in 3 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:0378-6985-01	100 in 1 CARTON		
1		3 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
Exempt device	CCQ	10/12/2009	

SODIUM CHLORIDE

nebulizer (direct patient interface)

Product Information

Product Type	MEDICAL DEVICE	Item Code (Source)	NHRIC:0378-6986
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8 X) (SODIUM CATION - UNII:L4M0NH37)	SODIUM CHLORIDE	0.045 g in 5 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:0378-6986-01	100 in 1 CARTON		
1		5 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
Exempt device	CCQ	10/12/2009	

SODIUM CHLORIDE

nebulizer (direct patient interface)

Product Information

Product Type	MEDICAL DEVICE	Item Code (Source)	NHRIC:0378-6987
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8 X) (SODIUM CATION - UNII:L4M0NH37)	SODIUM CHLORIDE	0.135 g in 15 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:0378-6987-89	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
Exempt device	CCQ	10/12/2009	

Labeler - Mylan Pharmaceuticals Inc. (059295980)

Revised: 12/2016

Mylan Pharmaceuticals Inc.