

SALINE MIST- saline mist spray
Rebel Distributors Corp

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Saline Mist Drug Facts

Active ingredient

Sodium Chloride 0.65%

Keep Out of Reach of Children

Uses

For dry nasal membranes squeeze twice in each nostril as needed.
Upright delivers a spray; Horizontally a stream; Upside down a drop.

Warnings

The use of this dispenser by more than one person may spread infection.

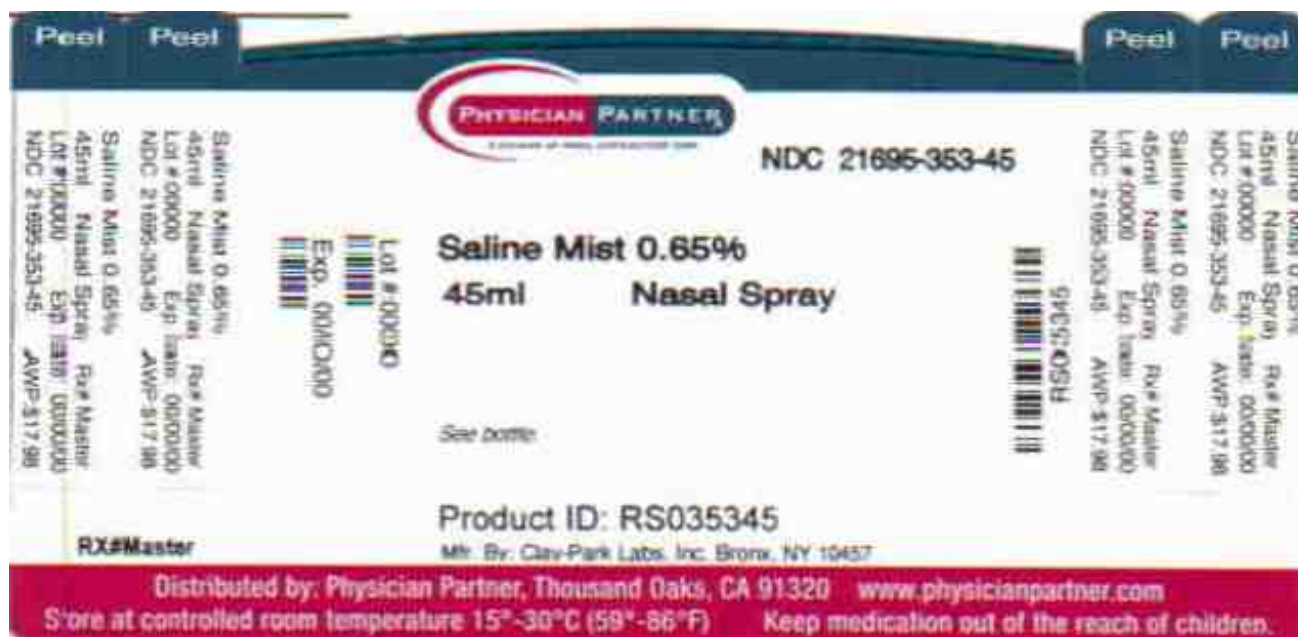
Directions

For dry nasal membranes squeeze twice in each nostril as needed.

Inactive ingredients

Purified Water, sodium chloride 0.65%, Disodium Phosphate, Phenylcarbinol, Monosodium Phosphate, Benzalkonium Chloride

Package/Label Principal Display Panel



SALINE MIST

saline mist spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21695-353(NDC:45802-357)
Route of Administration	NASAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	6.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM PHOSPHATE, DIBASIC, DIHYDRATE (UNII: 94255I6E2T)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
SODIUM PHOSPHATE, MONOBASIC ANHYDROUS (UNII: KH7I04HPUU)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21695-353-45	45 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part349	04/24/2009	

Labeler - Rebel Distributors Corp (118802834)

Establishment

Name	Address	ID/FEI	Business Operations
Rebel Distributors Corp		118802834	RELABEL, REPACK