SALINE NASAL- saline nasal spray
PURINEPHARMA LLC

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 NASAL SPRAY

Active Ingredient: Sodium Chloride 0.65%

For allergies, cold, flu, sinusitis, rhinitis and dry irritated nasal passages

Indications: For relief of dry nasal passages caused by sinus, cold and allergy medications, nasal surgery and dry air. Also relieves congestion by thinning mucus.

WARNING:
If pregnant or breast feeding, ask a health professional before use.

Use of this container by more than one person may spread infection.

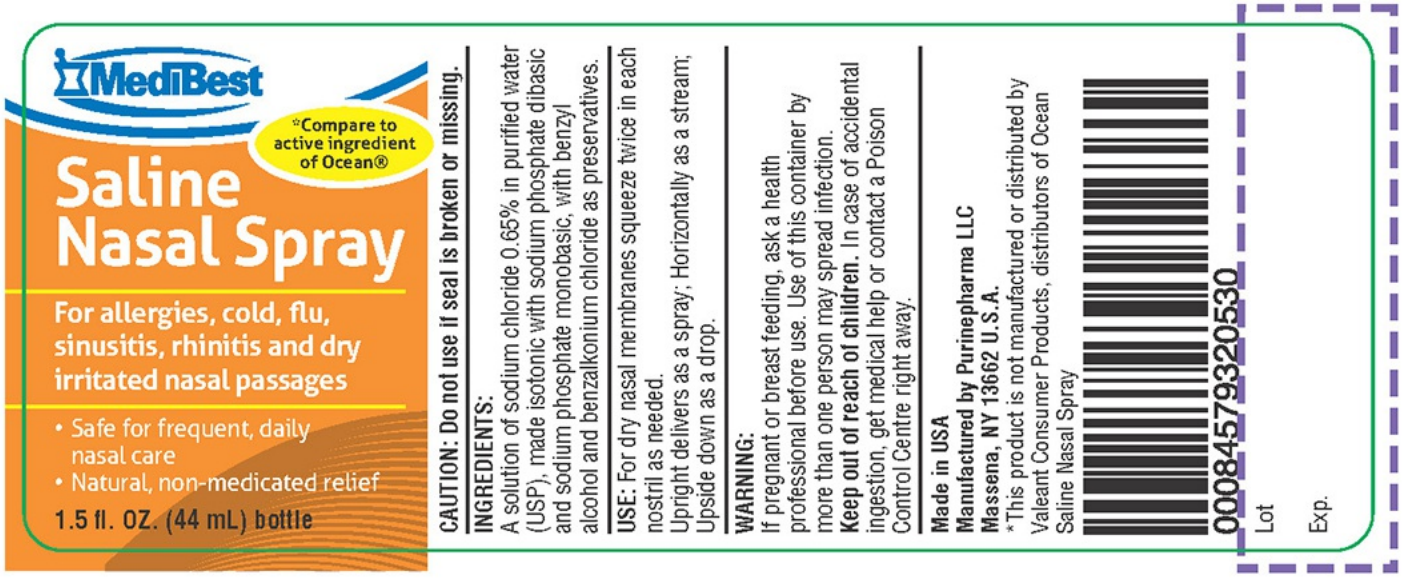
Keep out of reach of children. In case of accidental ingestion, get medical help or contact a Poison Control Centre right away.

Directions: For children and adults, squeeze bottle twice in each nostril as often as needed or as directed by doctor. For infants, use drop application. Hold bottle upright for spray, horizontally for stream and upside down for drop.

INGREDIENTS:
Sodium phosphate dibasic and sodium phosphate monobasic, with benzyl alcohol and benzalkonium chloride as preservatives.

Made in USA

Manufactured by Purinepharma LLC
Massena, NY 13662 U.S.A.
*This product is not manufactured or distributed by Valeant Consumer Products, distributors of Ocean Saline Nasal Spray



SALINE NASAL

saline nasal spray

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58599-036
Route of Administration	ORAL, Type 0: Not a Combination Product		

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**
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	
SODIUM PHOSPHATE, MONOBASIC, ANHYDROUS (UNII: KH7I04HPUU)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:58599-036-19	44 mL in 1 BOTTLE, SPRAY		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part349	02/07/2015	

Labeler - PURINEPHARMA LLC (019950491)

Registrant - PURINEPHARMA LLC (019950491)

Establishment

Name	Address	ID/FEI	Business Operations
PURINEPHARMA LLC		019950491	manufacture(58599-036)

Revised: 2/2015 PURINEPHARMA LLC