SALINE NASAL 1 FL OZ-sodium chloride 2.65% spray ALAINA HEALTHCARE PRIVATE LIMITED

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Bulk Listing: Allergy and Sinus: Hypertonic Saline Mist: CVS Health

Active ingredient

Sodium Chloride, 2.65%

Purpose

Nasal Wash to flush allergens and dust from Nasal Passages

Uses

Nasal congestion Removes inhaled irritants (dust, dirt, pollen) Moisturizes dry nasal passages

□ Warnings

Do not use if seal is broken or missing.

Warnings

Use of this product by more than one person may spread infection Contents under pressure Do not puncture or incinerate Avoid spraying in eyes

Keep out of reach of children. The use of this dispenser by more than one person may spread infection.

Directions

- Squeeze twice in each nostril as needed
- Upright delivers a spray, horizontally a stream, upside down a drop
- Take care not to aspirate nasal contents back into bottle
- If spray tip touches nose, rinse with hot water before replacing cap

Inactive ingredients

A hypertonic solution of purified water, potassium phosphate/Sodium hydroxide buffer, disodium ethylenediaminetetraacetic acid, benzalkonium chloride

Label

CVS HEALTH ALLERGY & SINUS 1 FL OZ

Hypertonic Saline Nasal Mist (Hypertonic Sodium Chloride 2.65% Solution)

KEEP OUT OF REACH OF CHILDREN, FOR NASAL USE ONLY

Batch No.: AHS9001 Mfg. Date: 11/2019 Exp. Date: 10/2021

Qty.: 24 Bottles Gross Weight:

Net Weight:

Neutral Code: HP/Drugs/MNB/16/931

Shipper No:

Manufacturer Labeler Code: Consignee Labeler Code: 76168

Manufacture By:

ALAINA HEALTHCARE PVT. LTD.

KHASRA No. 127-132,707/133 & 685/ 608/32

VILLAGE JHARMAJRI, BADDI, DISTT. SOLAN(H.P.) 174103

Consignee:

Velocity Pharma LLC Farmingdale, NY - 11735 USA



SALINE NASAL 1 FL OZ

sodium chloride 2.65% spray

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:73492-701

Route of Administration NASAL

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength
	SODIUM CHLORIDE (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	2.65 mg in 100 mL

Inactive Ingredients Ingredient Name Strength BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) EDETATE DISODIUM ANHYDROUS (UNII: 8 NLQ36 F6 MM)

WATER (UNII: 059QF0KO0R)

Packaging						
# Item Code	Package Description	Marketing Start Date	Marketing End Date			
1 NDC:73492-701-	24 in 1 BOX	11/19/2019				
1	30 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product					

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
unapproved drug other		11/19/2019			

Labeler - ALAINA HEALTHCARE PRIVATE LIMITED (858720927)

Establishment						
Name	Address	ID/FEI	Business Operations			
ALAINA HEALTHCARE PRIVATE LIMITED		858720927	manufacture (73492-701)			

Revised: 1/2021 ALAINA HEALTHCARE PRIVATE LIMITED