SALINE NASAL- sodium chloride 0.65% spray Lee Pharmaceuticals

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.

Drug Facts

Active ingredient

Sodium Chloride, 0.65%

Purpose

Moisturizer

\Box Uses

For dry nasal membranes

□*Warnings*

Do not use if seal is broken or missing.

IKeep out of reach of children

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

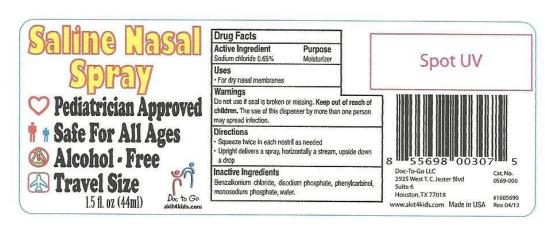
Directions

- Squeeze twice in each nostril as needed
- Upright delivers a spray, horizontally a stream, upside down a drop

Inactive ingredients

Benzalkonium chloride, Disodium phosphate, Phenylcarbinol, Monosodium phosphate, Water





SALINE NASAL

sodium chloride 0.65% spray

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:23558-0569

Route of Administration NASAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength SODIUM CHLORIDE (UNII: 451W47IQ8 X) (SODIUM CATION - UNII:LYR4M0 NH37, CHLORIDE ION - SODIUM CHLORIDE ION - CHLORIDE ION - IN 1 mL

Inactive Ingredients				
Ingredient Name	Strength			
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)				
SO DIUM PHO SPHATE, DIBASIC ANHYDRO US (UNII: 22ADO53M6F)				
BENZYL ALCOHOL (UNII: LKG8494WBH)				
SO DIUM PHO SPHATE, MO NO BASIC, ANHYDRO US (UNII: KH7104HPUU)				
WATER (UNII: 059QF0KO0R)				

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:23558-0569-0	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	07/01/2013	

Labeler - Lee Pharmaceuticals (056425432)

Registrant - Lee Pharmaceuticals (056425432)

Establishment							
Name	Address	ID/FEI	Business Operations				
Lee Pharmaceuticals		056425432	manufacture(23558-0569)				

Revised: 9/2012 Lee Pharmaceuticals