**SALINE NASAL 1.5OZ- 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.*

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***Drug Facts***

***Active ingredient***

Sodium Chloride, 0.65%

***Purpose***

Moisturizer

***Uses***

For dry nasal membranes

***Warnings***

Do not use if seal is broken or missing.

**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

***Inactive ingredients***

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

# SALINE NASAL 1.5OZ

sodium chloride 0.65% spray

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:23558-6896 |
| **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** |
| **BENZALKONIUM CHLORIDE** (UNII: F5UM2KM3W7) | |
| **SODIUM PHOSPHATE, DIBASIC ANHYDROUS** (UNII: 22ADO53M6F) | |
| **BENZYL ALCOHOL** (UNII: LKG8494WBH) | |
| **SODIUM PHOSPHATE, MONOBASIC, ANHYDROUS** (UNII: KH7I04HPUU) | |
| **WATER** (UNII: 059QF0KO0R) | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:23558-6896-1 | 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 | 10/01/2013 | |

## Labeler - Lee Pharmaceuticals (056425432)

## Registrant - Lee Pharmaceuticals (056425432)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Lee Pharmaceuticals | | 056425432 | manufacture(23558-6896) |

Revised: 11/2013 Lee Pharmaceuticals