SALINE NASAL 3OZ- 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.

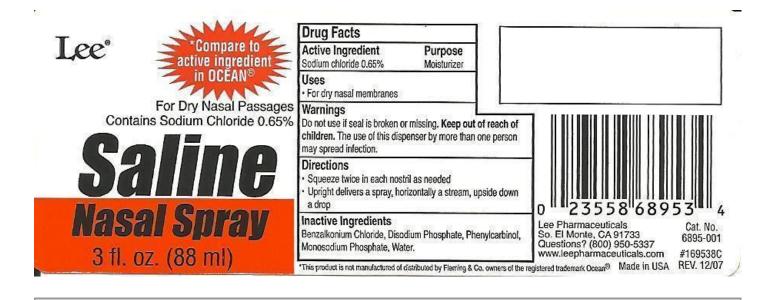
Keep out of reach of children. The use of this dispenser by more than one person may spread infection.

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 30Z

sodium chloride 0.65% spray

| Dro | duct | Inform | ation |
|-----|------|--------|-------|
| | | | |

| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:23558-6895 |
|--------------|----------------|--------------------|----------------|
|--------------|----------------|--------------------|----------------|

Route of Administration NASAL

Active Ingredient/Active Moiety

| Ш | Active ingredictionactive wholety | | | | |
|---|---|-------------------|----------------|--|--|
| Ш | 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 PHO SPHATE, DIBASIC ANHYDROUS (UNII: 22ADO53M6F) BENZYL ALCOHOL (UNII: LKG8494WBH) SODIUM PHO SPHATE, MO NO BASIC, ANHYDROUS (UNII: KH7I04HPUU) WATER (UNII: 059QF0K00R)

| Packaging | | | |
|--------------------|--------------------------|----------------------|--------------------|
| # Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 NDC:23558-6895-1 | 88 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(23558-6895) | |

Revised: 11/2013 Lee Pharmaceuticals