

NASAL- oxymetazoline hydrochloride
DR. FRIEDMAN'S NO MORE NOSEBLEED KIT INC.

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.

Active ingredient **Purpose**

Oxymetazoline hydrochloride 0.05% Nasal Decongestant

Uses

For the temporary relief of nasal congestion due to the common cold, hay fever or other upper respiratory allergies.

temporary relieves sinus congestion and pressure

shrinks swollen nasal membranes so you can breathe more freely

Warnings

Ask a doctor before use if you have

heart disease, high blood pressure, thyroid disease, diabetes, trouble urinating due to enlarged prostate gland

When using this product

do not use more than directed

do not use for more than 3 days. Use only as directed. Frequent or prolonged use may cause nasal congestion to recur or worsen

temporary discomfort such as burning, stinging, sneezing or an increase in nasal discharge may occur

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

Stop use and ask a doctor if symptoms persist.

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

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away at 1-800-222-1222

Directions

Adults and children 6 to under 12 years of age (with adult supervision): 2 or 3 sprays in each nostril not more often than every 10 to 12 hours. Do not exceed 2 doses in any 24-hour period.

Children under 6 years of age: ask a doctor.

To spray, squeeze bottle quickly and firmly. Do not tilt head backward while spraying. Wipe nozzle clean after use.

Other information

store at room temperature.

Inactive ingredients

Benzalkonium Chloride, benzyl Alcohol, edetate disodium, polyethylene glycol, Povidone, propylene glycol, Purified water, Sodium Phosphate dibasic, Sodium Phosphate monobasic.

Dr. Friedman's



SALINE NASAL SPRAY

Sodium Chloride 0.65%

Compare to the ingredients in Ocean



1.5 FL. OZ. (44 mL)

Do not use if imprinted seal around cap is broken or missing.

Ingredients:

benzalkonium chloride, benzyl alcohol, purified water, sodium chloride, sodium phosphate dibasic, sodium phosphate monobasic

Uses: Naturally provides instant, soothing relief to irritated nasal passages due to colds, allergies, dry air, pollution, smoke, air travel, and use of decongestants/steroidal sprays.

Warnings:

If pregnant or breastfeeding, ask a health professional before use.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away at 1-800-222-1222.

Directions: For children and adults, squeeze bottle twice in each nostril as often as needed or as directed by physician. For infants, use drop application. Hold bottle upright for spray, horizontally for stream, and upside down for drop. The use of this dispenser by more than one person may spread infection.

Store at room temperature 20° to 25° (68° to 77° F).

*This product is not manufactured or distributed by Valeant Pharmaceuticals North America LLC, owners of the registered trademark Ocean.

Distributed by:
7545 E Angus Dr
Scottsdale AZ 85251

70415DFLR



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68163190415

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LOT: No Varnish in this area
DO NOT PRINT BOX
EXP:

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NASAL

oxymetazoline hydrochloride kit

Product Information

| | | | |
|---------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:73169-002 |
|---------------------|----------------|---------------------------|---------------|

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:73169-002-01 | 1 in 1 PACKAGE; Type 1: Convenience Kit of Co-Package | 06/07/2019 | |

Quantity of Parts

| Part # | Package Quantity | Total Product Quantity |
|--------|------------------|------------------------|
| Part 1 | | 1 |
| Part 2 | | 1 |
| Part 3 | | 1 |
| Part 4 | | 1 |

Part 1 of 4

NO MORE NOSEBLEED

oxymetazoline hydrochloride liquid

Product Information

| | |
|-------------------------|---------------|
| Item Code (Source) | NDC:73169-001 |
| Route of Administration | TOPICAL |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------------------|---------------------|
| OXYMETAZOLINE HYDROCHLORIDE (UNII: K89MJ0S5VY) (OXYMETAZOLINE - UNII:8VLN5B44ZY) | OXYMETAZOLINE HYDROCHLORIDE | 0.05 g in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) | |
| BENZYL ALCOHOL (UNII: LKG8494WBH) | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| POVIDONE (UNII: FZ989GH94E) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| WATER (UNII: 059QF0KO0R) | |
| SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F) | |
| SODIUM PHOSPHATE, MONOBASIC, ANHYDROUS (UNII: KH7I04HPUU) | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part341 | | |

Part 2 of 4

SODIUM CHLORIDE 0.65% - NASALSALINE SPRAY

moisturizing

Product Information

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| Cosmetic | | | |

Part 3 of 4

VASELINE PETROLEUM JELLY

moisturizing

Product Information

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| Cosmetic | | | |

Part 4 of 4

BLEEDCEASE

other personal cleanliness products

Product Information

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| Cosmetic | | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part341 | 06/07/2019 | |

Labeler - DR. FRIEDMAN'S NO MORE NOSEBLEED KIT INC. (117075364)

Registrant - DR. FRIEDMAN'S NO MORE NOSEBLEED KIT INC. (117075364)

Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---------|-----------|------------------------|
| DR. FRIEDMAN'S NO MORE NOSEBLEED KIT INC. | | 117075364 | manufacture(73169-002) |

Revised: 1/2021

DR. FRIEDMAN'S NO MORE NOSEBLEED KIT INC.