SINUCLEANSE STERILE SALINE MIST- sodium chloride spray ASCENT CONSUMER PRODUCTS, INC

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.

SinuCleanse Sterile Nasal Saline Mist

Active Ingredient

Sodium Chloride 3%
Sterile, Hypertonic Saline Solution,
Sodium Bicarbonate to adjust pH

Purpose

Nasal Wash

Uses

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

Directions

Adults and children 4 years and over: Use as often as needed Children under 4 years: Consult a physician See directions on can for complere instructions

For nasal use only.

Before use, expel a shoet stream of mist into the air. Insert tip of nozzle into one nostril and press down on the textured area at the base of the nozzle so that a gentle mist coats nasal passages. Blow your nose very gently to clear the mucus out. Repeat for the other nostriil.

To flush and irrigate, tilt head to the side over sink. Insert top of nozzle into the top nostril, pressing down on the textured area at the base of the nozzle so that a gentle mist fills sinus passages and flows out the opposite nostril. Repeat in other nostril.

Wipe nozzle after each use.

Warnings

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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 chlidren.

Other Information

Store between 59 and 86 degree F

Inactive ingredients

Purfied Water

QUESTIONS?

1-888-547-5492



Drug Facts

Active ingredients

Purpose

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- 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

Directions

Adults and children 4 years and over:

Use as often as needed

Children under 4 years: Consult a physician See directions on can for complete instructions

Other information

- Store between 59° and 86° F (15° and 30° C). ■ See bottom of can for lot # and expiration date
- Inactive ingredients

Purified Water

Questions?

1-888-547-5492

ACP#00-50560-201-00

DVF# SCEXBOV1

Distributed by: Ascent Consumer Products Melville, NY 11747 @2020

SinuCleanse® Allergy & Sinus Relief Nasal Mist allows you to Breathe Easier with the Power of Salt. It's all-natural, preservative & steroid free formula quickly moisturizes dry nasal passages and aids in the removal of allergens & other irritants, providing relief of nasal congestion & sinus symptoms associated with year-round allergies. It may be used as often as needed day or night, with prescriptions & OTC medicines without the worry of side effects or drug interactions and is manufactured in the USA at an FDA registered drug facility to ensure safety & efficacy.

Directions for Use

Non-Habit Forming, May Be Used As Often As Needed

For Nasal Use Only. Before and after each use, expel a short stream of mist into the air to clear nozzle.

Gently insert tip of nozzle into one nostril and press down on the textured area at the base of the nozzle so that a gentle mist coats nasal passage. Blow your nose very gently to clear the mucus out. Repeat for the other nostril.







*Allergy & Sinus (hypertonic) saline contains a higher concentration of salt which draws water out of swollen nasal tissues for better drainage. A hypertonic saline solution may cause temporary stinging and burning. If this occurs consider using an isotonic 0.9% odium chloride solution product such as SinuCleanse Daily Care Nasal Mist.

For more information and to see our other SinuCleanse®products visit: www.sinudeanse.com



SINUCLEANSE STERILE SALINE MIST

sodium chloride spray

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:42829-505

Route of Administration NASAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength

646011505600

SODIUM CHLORIDE (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32ZN48698) **SODIUM CHLORIDE** 3 g in 100 g

Inactive Ingredients

Ingredient Name Strength

WATER (UNII: 059QF0KO0R)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42829- 505-60	129 g in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/13/2021	
2	NDC:42829- 505-75	213 g in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	01/01/2022	

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
unapproved drug other		03/13/2021			

Labeler - ASCENT CONSUMER PRODUCTS, INC (078396381)

Revised: 1/2022 ASCENT CONSUMER PRODUCTS, INC