

**SINUCLEANSE- sodium bicarbonate, sodium chloride powder, for solution
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.

Purpose

Nasal Wash

Uses

Temporarily relieves symptoms associated with sinusitis, cold, flu or allergies

-Sneezing

-Nasal stuffiness

-Runny nose

-Post nasal drip

Removes inhaled irritants (dust, pollen)

Removes nasal and sinus drainage

Helps reduce swelling of nasal membranes

Moisturizes dry nasal passages

Keep out of reach of children

Warnings

Stop use and ask a doctor if washing is uncomfortable or symptoms are not relieved.

Do not use unfiltered tap water. see instructions inside box for proper water sources

Do not use if nasal passages are completely blocked or if you have an ear infection or blocked ears.

Directions

Adults and children 4 years and over: Use 1/2 -1 packet per 4 fl oz (120 mL) up to every 2 hours as needed.

Children under 4 years: Consult a physician

See enclosed instruction sheet for complete directions and proper use.

Important Note: SinuCleanse Saline Packets contain 3 grams of

pharmaceutical grade salt. Using the calculations in the chart, you can prepare either an Isotonic or Hypertonic Solution. Since contents of other manufacturer's Salt Packets may vary, please check with their directions for Isotonic or Hypertonic use.

Active ingredients

(in each packet)

Sodium Bicarbonate USP (700 mg)

Sodium Chloride USP (2300 mg)

Inactive ingredients

None

Other Information

- Inspect saline packets for integrity
- Do not use saline packets if open or torn
- Protect saline packets from excessive heat and moisture
- See saline packets or box for lot # and expiration date

Questions?

1-888-547-5492

- See enclosed instruction sheet for complete directions and proper use

Dry Ingredients for
SinuCleanse
Natural Saline Solution

Active Ingredients:
Sodium Bicarbonate, Sodium Chloride
Inactive Ingredients: None

MADE IN U.S.A. NET WT 0.1 OZ (3g)

7-3109-001
Distributed By:
ASCENT CONSUMER PRODUCTS INC.
Melville, NY 11747 ©2013
Questions or Additional Information
www.sinucleanse.com
Not labeled for individual sale
See instruction sheet for proper use & directions
EXP. DATE/LOT

SINUCLEANSE

sodium bicarbonate, sodium chloride powder, for solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42829-401
Route of Administration	NASAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM BICARBONATE (UNII: 8MDF5V39QO) (SODIUM CATION - UNII:LYR4M0NH37, BICARBONATE ION - UNII:HN1Z RA3Q20)	SODIUM BICARBONATE	700 mg in 3000 mg
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37)	SODIUM CHLORIDE	2300 mg in 3000 mg

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42829-401-01	3000 mg in 1 PACKET; Type 0: Not a Combination Product	02/01/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		02/01/2015	

Labeler - ASCENT CONSUMER PRODUCTS, INC. (078396381)

Revised: 1/2025

ASCENT CONSUMER PRODUCTS, INC.