

**SINUCLEANSE NETI-POT- sodium bicarbonate, sodium chloride
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 packets per 8 fl oz (240 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.

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 number and expiration date

Questions?

1-888-547-5492

Active ingredients

(in each packet)

Sodium Bicarbonate USP (700 mg)

Sodium Chloride USP (2300 mg)

Inactive Ingredients

None

Instructions for Use of the SinuCleanse Neti Pot

Directions: Read through entire section before using for the first time.

1. Empty the contents of one SinuCleanse Saline Wash packet into the SinuCleanse Neti Pot. First-time users should start with 1/2 packet of the SinuCleanse dry ingredients. As you become more accustomed to the system, work up to using 1 full packet. Additional packets may be purchased from your nearest pharmacy.

2. Fill the pot halfway or to the middle of the indentation with a proper water source.* This makes 1/2 cup (4 oz.) solution.

3. Stir thoroughly until dry ingredients have completely dissolved.

4. Proper head position allows solution to flow through the nose by gravity.

- Lean over the sink with your head bent down so you are looking directly into the basin.

Holding the pot in your right hand, gently insert the spout into your right nostril so that it

forms a comfortable seal.

- Rotate your head so that the right nostril is directly above the left. The forehead should

remain higher than the chin. Raise the handle of the pot so that the solution enters the right

nostril. In a few moments, the solution will begin to drain out the left nostril into the sink.

Do not inhale or "snort" solution into the nose - breathe through your mouth.

5. When the pot is empty, exhale through both nostrils to clear them

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42829-402
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42829-402-30	1 in 1 KIT; Type 1: Convenience Kit of Co-Package	02/01/2015	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	30 PACKET	90000 mg

Part 1 of 1**SINUCLEANSE**

sodium bicarbonate, sodium chloride powder, for solution

Product Information

Item Code (Source)	NDC:42829-401
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Route of Administration	NASAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37)	SODIUM CHLORIDE	2300 mg in 3000 mg
SODIUM BICARBONATE (UNII: 8MDF5V39QO) (SODIUM CATION - UNII:LYR4M0NH37, BICARBONATE ION - UNII:HN1ZRA3Q20)	SODIUM BICARBONATE	700 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 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		04/01/2013	

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)

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ASCENT CONSUMER PRODUCTS, INC.