SINUCLEANSE SQUEEZE- 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 form 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 Squeeze

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

- 1. Remove the cap from the SinuCleanse Squeeze bottle.
- 2. Pour the pre-mixed saline dry ingredients into the SinuCleanse Squeeze Bottle. First-time users should start with 1 packet of the saline dry ingredients. As you become more accustomed to the system, work up to using 2 full packets. Additional packets may be purchased from your nearest pharmacy.
- 3. Fill the bottle with a proper water source * leaving approximately 1/2 inch of air at the top of the bottle. This makes 1 cup (8 oz.) of solution.
- 4. Tighten the cap on the bottle securely, place one finger over the tip of the cap and gently

shake the bottle until the dry ingredients have completely dissolved.

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

the tip of the cap up to the right nostril and gently insert the tip so that it forms a comfortable

seal. Aim the tip at the back of your head, not at the top of your head.

6. Squeeze the bottle gently so that the solution enters the right nostril. Do not inhale or "snort"

the solution into the nose - breathe through your mouth.

7. In a few moments the solution will begin to drain out of the left nostril. Continue to squeeze

the bottle gently until you have used approximately half of the solution.

- 8. Remove the tip of the bottle from your nostril, then exhale through both nostrils to clear them of excess mucus and solution. Gently blow your nose into a tissue.
- 9. Repeat the procedure on the left nostril with the remaining solution.
- 10. A small amount of solution will remain at the bottom of the bottle. Discard the remaining solution.
- 11. Thoroughly rinse the bottle after each use with water that has been distilled, sterilized, filtered or previously boiled and leave the bottle open to air dry completely. The SinuCleanse Squeeze Bottle is also top-rack dishwasher safe. Hints for a more comfortable nasal wash
- Begin using the SinuCleanse System slowly. A full pot or bottle of solution on each side is not necessary to receive the full benefit.
- -If the solution is too warm or too cold, the nasal wash will be uncomfortable.
- -If stinging or irritation occurs, try using 1/2 of a packet of dry ingredients for the Neti Pot or 1 packet per Squeeze Bottle of the saline dry ingredients. Gradually work up to using the solution at full strength. Do not use less than 1/2 packet for the Neti Pot or 1 packet per Squeeze bottle.
- -If you experience ear discomfort after use, try to blow your nose more gently after the wash. If the problem persists, the openings of your Eustachian tubes may be particularly wide and the use of the SinuCleanse System may need to be discontinued.
- -Breathe continuously through the mouth when using the SinuCleanse system to avoid solution draining from the back of the nose into the mouth.
- -Some people experience irritation of the skin just insdie the nostrils with repeated nasal washing. Applying a thin layer of aloe to the inside of the nostrils before or after the nasal wash will be soothing.

ACP#:00-40530-101-02 Ascent Consumer Products SinuCleanse Squeeze R13 4/15/2014



SinuCleanse.

SinuCleanse* Nasal Wash products were developed by a leading U.S. Ear, Nose & Throat Physician as an all-natural way to immediately relieve nasal congestion, and sinus symptoms without the worry of any harmful side-effects or drug interactions.

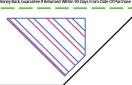
Relieves Symptoms from: sal Congestion - Sinusitis and Rhinitis rre - Cold and Flu - Nasal Dryness - Allergies

to ensure Quality, Safety and Effectiveness. Should lace an locknois or Hypertonic Solution? SimuCleanes Pharmaceutical Grade Saline Packets can be used a SimuCleanes Pharmaceutical Grade Saline Packets can be used a consult with your brystician for beat use. With the guide below or consult with your brystician for beat concentrated salt solution. An Isotonic solution creates a mild, less concentrated salt solution concentration of your body and may be more comfortable to use the properties of the properties of the properties of the Antipole Control of the Control of the Control of the concentration of your body and may be more confortable to use the properties of the Control of control of the Control of the control of the Control of control of the Control of contro

Isotonic Solution	1 SinuCleanse® Saline Packet per 8 fl oz. (240mL)	
Hypertonic Solution	2 SinuCleanse® Saline Packets per 8 fl oz. (240mL)	

SinuCleanse® Genie Style Neti Pot SinuCleanse® Refill Saline Packets (60 & 100 Count)

Money Back Guarantee If Returned Within 90 Days From Date Of Purchas











SINUCLEANSE SQUEEZE

sodium bicarbonate, sodium chloride kit

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:42829-405

Packaging Marketing Start Date Marketing End Date Item Code **Package Description** 1 NDC:42829-405-30 1 in 1 KIT 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

Route of Administration NASAL

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:HN1Z RA3Q20)	SODIUM BICARBONATE	700 mg in 3000 mg		

Inactive Ingredients			
	Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)			

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		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	Application Number or Monograph	Marketing Start	Marketing End	
Category	Citation	Date	Date	

unapproved drug other	02/01/2015	

Labeler - ASCENT CONSUMER PRODUCTS, INC. (078396381)

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