

**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.*

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**Sinucleanse**

Active Ingredients

(in each packet)

Sodium Bicarbonate USP 700 mg

Sodium Chloride USP 2300 mg

Purpose

Nasal Wash

Uses

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

- Sneezing
- Runny nose
- Nasal stuffiness
- Post nasal drip
- Removes inhaled irritants (dust, pollen)
- Promotes nasal and sinus drainage
- Helps reduce swelling of nasal membranes
- Moisturizes dry nasal passages

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.

When using this product:

- Use by only one person
- Wash with soap and water after each use

-Top rack of dishwasher safe

-Do not heat in microwave

Keep out of reach of children

Directions

Adults and children 4 years and over: use 1/2 - 1 packet per 4 fl oz (120 mL) up to every two 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 # and expiration date

Inactive Ingredients

None

Questions?

1-888-547-5492

12<sup>25</sup>/<sub>32</sub>

ACP #: 00-40860-01-03  
Accent Consumer Products  
SinuCleanse 60 Ct. Saline Refill Pk  
11/20/2014



10<sup>25</sup>/<sub>32</sub>

**SinuCleanse**  
Products

Developed and Recommended by a Leading Ear Nose & Throat Physician

**60 Refill Saline Packets**

**Relieves Symptoms From:**  
Nasal Congestion • Sinusitis and Rhinitis  
Sinus Pressure • Cold and Flu • Nasal Dryness • Allergies

The SinuCleanse® Pharmaceutical Grade Saline Packets contain a balanced, preservative free, ultra-fine salt packets which dissolve instantly, making nasal washing gentle, simple and easy.

SinuCleanse® products are made only from pure sea salt and distilled water. SinuCleanse® products are used only for nasal irrigation and are not intended for oral use. SinuCleanse® products are used only for nasal irrigation and are not intended for oral use. SinuCleanse® products are used only for nasal irrigation and are not intended for oral use.

**Should I use an Isotonic or Hypertonic Solution?**  
SinuCleanse® Pharmaceutical Grade Saline Packets can be used as either isotonic or hypertonic solutions. Check with the guide below or consult with your physician for best use.

An isotonic solution creates a mild, less concentrated salt solution of 0.9% of Sodium Chloride per mL of water, which has the same salt concentration of your body and may be more comfortable to use for some people initially than a more concentrated hypertonic solution.

A hypertonic solution is a hypertonic solution creates a higher concentration salt solution which is similar to the salt content of ocean water.

Isotonic Solution	Hypertonic Solution
1 SinuCleanse® Saline Packet per 100 mL of Water	2 SinuCleanse® Saline Packets per 100 mL of Water

**Important Note:** SinuCleanse® Saline Packets contain 1 gram of pharmaceutical grade salt. Using the instructions in the chart above, you can prepare either an isotonic or Hypertonic Solution. Since contents of other manufacturers' Salt Packets may vary please check with their directions for isotonic or hypertonic use.

SinuCleanse® Saline Packets can be used with SinuCleanse® Products or other nasal wash products.  
Look For us under SinuCleanse® Products, or visit us online at [www.accentconsumer.com](http://www.accentconsumer.com)

SinuCleanse® 60ct Single Use Per Packet  
SinuCleanse® 60ct Single Use Per Packet  
SinuCleanse® 60ct Single Use Per Packet (750 count)

Always Use Cleanse® Product with 100% Pure Distilled Water

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SinuCleanse® Saline Packets can be used with SinuCleanse® Products or other nasal wash products.  
Look For us under SinuCleanse® Products, or visit us online at [www.accentconsumer.com](http://www.accentconsumer.com)

SinuCleanse® 60ct Single Use Per Packet  
SinuCleanse® 60ct Single Use Per Packet  
SinuCleanse® 60ct Single Use Per Packet (750 count)

Always Use Cleanse® Product with 100% Pure Distilled Water

**Drug Facts**

Active Ingredients (in each packet)	Purpose
Sodium Chloride USP (200 mg)	Nasal Wash
Sodium Citrate USP (250 mg)	

**Uses**  
Temporarily relieves symptoms associated with:  
■ Short-term cold, flu or allergies  
■ Sinusitis  
■ Nasal dryness  
■ Irritation of the nasal mucous membranes  
■ Promotes more and more drainage  
■ Helps reduce allergic rhinitis symptoms  
■ Moistens dry nasal passages

**Warnings**  
Stop use and ask a doctor if swelling, pain, or tenderness or irritation does not subside.  
Do not use without first reading the instructions inside the product container.  
Do not use if the packet is not properly sealed or if you have an ear infection (otitis) or Eustachian tube dysfunction.

**Directions**  
Adults, children & teens: Use 1-2 packets per 100 mL (2-40 mL) of water and use.  
Children under 4 years: Consult a doctor.

**Other Information**  
■ Insert salt packets in nostrils.  
■ Do not use salt packets in eyes or ears.  
■ Never use salt packets from excessive heat and moisture.  
■ Use only one packet at a time for 1-2 minutes per day.

**Inactive Ingredients**  
None

**Questions?**  
1-888-547-5492

EXP. BY: \_\_\_\_\_

MADE IN U.S.A.

Distributed by: Accent Consumer Products • 14416 N. 117th • 98114

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ACP #: 00-40860-01-03

ACP #: 00-40800-101-01  
 Ascend Consumer Products  
 SinuCleanse Saline Refills 100 Ct R12  
 4/15/2014

Developed and Recommended by a Leading Ear, Nose & Throat Physician

**SinuCleanse<sup>®</sup>**  
Products

Natural Soothing Relief from Nasal Congestion & Sinus Symptoms

**100 Refill Saline Packets**

**Clinically Proven Safe & Effective**

**100% All-Natural, Preservative & Gluten Free**

**For use with Nasal Wash Systems**

**Hypertonic or Isotonic use** (see side panel for instructions)

A Safe and Easy Way to Breathe Better... Naturally

**100 All-Natural Pharmaceutical Grade Saline Packets NET WT 0.1 OZ (3 g) each**

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Print as CMYK

# SINUCLEANSE

sodium bicarbonate, sodium chloride powder, for solution

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:42829-408
<b>Route of Administration</b>	NASAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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<b>SODIUM BICARBONATE</b> (UNII: 8MDF5V39QO) (SODIUM CATION - UNII:LYR4M0NH37, BICARBONATE ION - UNII:HN1Z RA3Q20)	SODIUM BICARBONATE	22.2 mg in 100 mg
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37)	SODIUM CHLORIDE	77.8 mg in 100 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42829-408-00	100 in 1 CARTON	12/01/2015	
1		3000 mg in 1 PACKET; Type 0: Not a Combination Product		

### 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: 5/2024

ASCENT CONSUMER PRODUCTS, INC.