

**SINUCLEANSE MICRO-FILTERED NASAL WASH SYSTEM- sodium chloride,
sodium bicarbonate
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.

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 reduced.

When used with tap water see instructions inside box for proper water sources.

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 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 no. and expiration date

Inactive ingredients: none

Questions?

1-888-547-5492

Filter Data

Model #'s:

91-40630, 97-40630, 98-40630

Manufacturer:

Ascent Consumer Products Inc.

Melville NY 11737

888-547-5492

Distributed by:

See Box for Information

Filter Type:

Mechanical Cyst Reduction Filter

Maximum Operating Temperature:

100 degrees Fahrenheit

Maximum Working Pressure:

5 psi

Maximum Service Life:

50 gallons

This product has been tested and certified to meet NSF/ANSI Standard 53, a drinking water standard, for cyst reduction of 99.95% and to be lead free.

For more information from the Centers for Disease Control and Prevention (CDC)

on water filters and sinus washing visit the CDC web site at:

<http://www.cdc.gov>.

Micro-Filtered

Sinus Wash System

Please read instructions thoroughly before using and keep for future reference.

NEW!

BUILT IN WATER

FILTER

About the Micro-Filtered Sinus Wash System

The Micro-Filtered Sinus Wash System is a revolutionary new product that makes receiving the proven benefits of sinus washing easier than ever. The built in water filter meets the CDC recommendation for sinus washing with tap water*. This provides peace of mind, while also eliminating the cost of bottled water or the inconvenience of boiling and pre-filtering tap water. It also allows for easier temperature control of the saline solution for a soothing and more comfortable sinus wash

The patent pending Micro-Filtered System incorporates additional innovations to maximize the comfort and convenience of sinus washing:

- Inverted filter technology with anti-backflow valve uses a combination of gravity and positive pressure to provide an easy to control and comfortable flow of the saline solution.
- Ergonomically designed bottle and soft nasal tip are comfortable to use and easy to clean.

Frequently asked questions and important information about the Micro-Filtered Sinus Wash System Warning: Do not use Micro-Filtered System if nasal passages are completely blocked.

Preparing the Micro-Filtered System for first use

Before first use rinse the bottle with warm tap water and empty. Next fill bottle with warm tap water and place cap on bottle and tighten securely. Holding the assembled bottle and cap over the sink, invert so comfort tip faces up and squeeze bottle several times until bottle is empty and no water flows from the comfort tip. Repeat the filling and emptying process two additional times. The Micro-Filtered System is now ready for use.

What type of water can be used in the Micro-Filtered System?

In addition to distilled water or commercially bottled water the Micro-Filtered System can be used with tap water. **WARNING:** The Micro-Filtered System is intended as a final filter for tap water that is known to be safe for drinking.

How do I clean the Micro-Filtered System?

Do not clean any part of the Micro-Filtered System in the dishwasher.

Cleaning the bottle: Rinse the bottle out with water after each use and allow to dry.

Cleaning the comfort tip: Remove tip and clean with soap and water after each use. Replace tip after cleaning.

Cleaning the cap: The outside of the cap can be rinsed with water and dried.

Can I share the Micro-Filtered System with friends and family?

The Micro-Filtered System is intended for individual use and not to be shared.

How do I clean the Micro-Filtered System?

Do not clean any part of the Micro-Filtered System in the dishwasher.

Cleaning the bottle: Rinse the bottle out with water after each use and allow to dry.

Cleaning the comfort tip: Remove tip and clean with soap and water after each use. Replace tip after cleaning.

Cleaning the cap: The outside of the cap can be rinsed with water and dried.

Should I use an Isotonic or Hypertonic solution?

The Micro-Filtered System can be used with the enclosed saline packets to make either an Isotonic or Hypertonic solution. An Isotonic solution has a salt concentration similar to your body and some people find this more comfortable to use. A Hypertonic solution is more concentrated, similar to the salt concentration of ocean water. Both are beneficial to your sinus and nasal health.

Check with the guide below or consult with your physician for best use.

Check with the guide below or consult with your physician for best use.

Isotonic Solution 1 Saline Packet per

8 fl oz

Hypertonic Solution

2 Saline Packets per

8 fl oz

Helpful hints for a more comfortable sinus wash experience:

- Begin using the Micro-Filtered System slowly – especially with children. A full bottle of solution is not necessary to receive the full benefit.
- If the solution is too warm or too cold, the Sinus Wash will be uncomfortable.
- If stinging or irritation occurs, try using 1 packet of dry ingredients per bottle. Gradually work up to using the solution at full strength using 2 full packets per bottle. Do not use less than 1 packet.
- If you experience ear discomfort after use, try to blow your nose gently after the wash. If the problem persists, the openings of your Eustachian tubes may be particularly wide and use of the system should be discontinued.
- Breathe continuously through the mouth when using the Sinus Wash System to avoid solution draining from the back of the nose into the mouth.

Instructions for Use:

1. Wash your hands and **make sure the Micro-Filtered System has been prepared**

according to the instructions above before first use.

2. Pour the contents of the saline packet(s) into the bottle. First-time users should start with 1 packet to make an Isotonic solution. As you become more accustomed to using the system, you may work up to using 2 full packets for a Hypertonic solution. Additional packets may be purchased online or from your nearest pharmacy.

3. Fill the bottle with warm tap water to the 8 oz mark indicated on the bottle. Test water temperature before using.

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 comfort tip 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. When finished hold the system inverted over sink and squeeze several times to remove solution remaining in cap.

11. Holding the cap assembly over the sink unscrew filter (B) by turning the white ring on bottom

of cap counter clockwise while holding cap (A). Empty any remaining solution into the sink

and allow to dry. Reassemble the filter making sure the black O-ring (C) is seated above the

filter base threads as shown in the illustration below. After each use please clean system.

Clean the bottle: Rinse the bottle out with water and allow to dry.

Clean the comfort tip: Remove tip and clean with soap and water and reinstall.

Clean the cap: The outside of the cap can be rinsed with water and dried.

Keep Box and Instruction Sheet for Future Reference

SALES LIMITED TO NET WT. & SEAL IS BROKEN OR MISSING

SinuCleanse[®] Products

Natural Soothing Relief from Nasal Congestion & Sinus Symptoms

Micro-Filtered Nasal Wash System

Built in water filter meets the CDC recommendation for nasal washing with tap water*



NEW!
BUILT IN WATER FILTER

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Natural Soothing Relief from Nasal Congestion & Sinus Symptoms



Micro-Filtered Nasal Wash System

Built in water filter meets the CDC recommendation for nasal washing with tap water*

Soft Comfort Tip
BPA & Latex Free



*This product has been tested and certified to meet NSF/ANSI Std. 53, a drinking water standard, for cyst reduction.

30 100% All-Natural Pharmaceutical Grade Saline Packets NET WT. 0.1 OZ (3 g) each

1 Micro-Filtered Nasal Wash System



ACPT 00-80990-0101-00

Drug Facts

Active Ingredients (in each packet)
Sodium Bicarbonate USP 3.0 mg
Sodium Chloride USP 210.0 mg

Uses
Temporarily relieves symptoms associated with:
 Nasal congestion
 Runny nose
 Post-nasal drip
 Sneezing
 Facial stuffiness
 Runny nose
 Post-nasal drip
 Red, swollen, irritated nasal passages
 Dry, itchy nose and throat
 Red, swollen, irritated nasal passages
 Dry, itchy nose and throat

Warnings
 Stop use and ask a doctor if multiple or severe symptoms are not relieved.
 When used with tap water, use the instructions inside box for proper use.
 Do not use if nasal passage is completely blocked or if you have a cold, infection or sinus infection.
 When using this product:
 Do not use with eye contact.
 Use the bottle with soap and water after each use.
 Do not use in microwave.
 Keep out of reach of children.

Directions
 Adults and children 12 years and over: Use 2 packets per side (24 ml) 2-3 times per day.
 Children 6-11 years: Use 1 packet per side (12 ml) 2-3 times per day.
 Children under 6 years: Consult a physician.

Other information
 Do not use saline packets for irrigation.
 Do not use saline packets, frozen or tampered.
 Do not use saline packets from sources in heat and moisture.
 See saline packets or box for lot / and expiration date.

Inactive Ingredients
 None.

Questions?
 1-800-447-5492

DP1 / MPS1

EXP. DATE LOT

Saline Packets Made in the USA
in an FDA Registered Drug Facility

Distributed by: Allent Consumer Products, Melville, NY 11747 ©2015



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BUILT IN WATER
FILTER

SinuCleanse[®] Products

Natural Soothing Relief for
Nasal Congestion & Sinus Symptoms

Micro-Filtered Nasal Wash System

**Built in water filter meets the
CDC recommendation for nasal
washing with tap water***

- Soft Comfort Tip
- BPA & Latex Free

 *This product has been tested and certified to meet NSF/ANSI Std. 53, a drinking water standard, for cyst reduction.

30 100% All-Natural Pharmaceutical Grade Saline Packets NET WT. 0.1 oz (3 g) each

7 Micro-Filtered Nasal Wash System

SinuCleanse[®]

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

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

The SinuCleanse[®] Micro-Filtered Nasal Wash System is a revolutionary new product that makes receiving the proven benefits of Nasal Wash[®] greater than ever. The built-in water filter meets the CDC recommendation for nasal washing with tap water. It provides peace of mind while also eliminating the cost of bottled water or the inconvenience of both. And, one-filtering tap water also allows for user temperature control of the saline solution for a soothing and more comfortable nasal wash.

- The patent pending Micro-Filtered System incorporates additional innovations to maximize the comfort and convenience of nasal washing.
- Inverted filter technology with anti-backflow valve uses a combination of gravity and positive pressure to provide an easy to control and comfortable flow of the saline solution.
- Ergonomically designed bottle and soft nasal tip are comfortable to use and easy to clean.

SinuCleanse[®] Products utilize the highest quality ingredients and are assembled in FDA Registered Facilities to ensure Quality, Safety and Effectiveness.

Important: Use an Isotonic or Hypertonic Solution!
The Micro-Filtered System can be used with the enclosed saline packets to make either an Isotonic or Hypertonic solution. An Isotonic solution has a salt concentration similar to your body and some people find this more comfortable to use. A Hypertonic solution is more concentrated, similar to the salt concentration of ocean water, both are beneficial to your sinus and nasal health.

Check with the guide below or consult with your physician for best use.

Isotonic Solution	1 SinuCleanse [®] Saline Packet per 1 oz (30 mL)
Hypertonic Solution	2 SinuCleanse [®] Saline Packets per 1 oz (30 mL)

Important Note: SinuCleanse[®] Saline Packets contain 3 grams of pharmaceutical grade salt. Use the calculation in the chart above, you can prepare either an Isotonic or Hypertonic Solution. Once contents of either manufacturer's Salt Packets may vary, please check with their instructions for isotonic or hypertonic use.

Look for our other SinuCleanse[®] Products, or visit www.sinucleanse.com

SinuCleanse[®] Gentle Style Net Pot
SinuCleanse[®] Refill Saline Packets (60 & 100 Count)
SinuCleanse[®] Squares
Money Back Guarantee: If Not Satisfied Within 90 Days, From Date Of Purchase

Printed in China


SINUCLEANSE MICRO-FILTERED NASAL WASH SYSTEM

sodium chloride, sodium bicarbonate kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42829-406
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42829-406-30	1 in 1 KIT	07/01/2015	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 PACKET	3000 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 BICARBONATE (UNII: 8MDF5V39QO) (BICARBONATE ION - UNII:HN1ZRA3Q20)	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
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1	NDC:42829-401-02	30 in 1 KIT		
1		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		07/01/2015	

Labeler - ASCENT CONSUMER PRODUCTS, INC. (078396381)

Revised: 1/2024

ASCENT CONSUMER PRODUCTS, INC.