

## **CVS- sodium chloride, sodium bicarbonate**

### **CVS Pharmacy**

*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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### **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.**

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
- 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

Prior to first use see enclosed instruction sheet for complete directions

**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

Model #'s:

91-40630, 97-40630, 98-40630

Manufacturer:

Ascent Consumer Products Inc. Melville NY 11737

888-547-5492

Filter Data

**Micro-Filtered Sinus Wash System**

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

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.

**NEW!**

**BUILT IN WATER FILTER**

**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>.**

Patent Pending

**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.

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

Patent Pending

### **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.

#### **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.



#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59779-867-30	1 in 1 KIT	07/01/2015	

### Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 PACKET	3000 mg
Part 2	1 CARTON	1

### Part 1 of 2

#### CVS

sodium bicarbonate, sodium chloride powder

### Product Information

Item Code (Source)	NDC:59779-408
Route of Administration	NASAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM BICARBONATE (UNII: 8MDF5V39QO) (BICARBONATE ION - UNII:HN1ZRA3Q20)	SODIUM BICARBONATE	22.8 mg in 100 mg
SODIUM CHLORIDE (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	77.8 mg in 100 mg

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		30 in 1 KIT		
1	NDC:59779-408-01	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		06/01/2013	

## Part 2 of 2

### INSTANT RELIEF MICRO-FILTERED SINUS WASH SYSTEM

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#### Product Information

Item Code (Source)	GS1:30707387763634
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#### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 KIT		
1	GS1:307073877636	1 in 1 CARTON; Type 1: Convenience Kit of Co-Package		

#### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
exempt device	KCJ		

#### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		07/01/2015	

**Labeler** - CVS Pharmacy (062312574)

Revised: 12/2016

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