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.

Active ingredients

(in each prefilled bottle)

Sodium Bicarbonate USP 700 mg }

Sodium Chloride USP 2300 mg }

Active ingredients

(in each packet)

Sodium Bicarbonate USP 700 mg }

Sodium Chloride USP 2300 mg }

Purpose

Nasal Wash

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Nasal Wash

Uses

Temporarily relieves symptoms associated with sinusitis, cold, flue 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 ear.

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

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
- Do not use if printed foil seal under cap on pre-filled bottle is broken or missing
- Protect saline packets from excessive heat and moisture
- See saline packets or box for lot number and expiration date

Inactive ingredients

(in each prefilled bottle)

Purified Water USP, Benzalkonium Chloride USP (Preservative)

Inactive ingredient

(in each packet)

none

Questions?

1-888-547-5492

Sinus Wash
Pre-Filled Ready to Use
Saline Sinus Wash Kit
Instructions
DO NOT
SINUS WASH
WITH UNFILTERED
TAP WATER.
See important note*

for proper water

sources.

Read through entire instruction sheet

before using for the first time.

* IMPORTANT NOTE

Do not sinus wash with unfi ltered tap water. Use either distilled, or sterile, or fi ltered (using a fi lter with an absolute pore size of 1 micron or smaller) or previously boiled water (boil water 1 minute or 3 minutes if at elevations above 6,500 feet, then allow to cool to body temperature).

Instructions for Use of the Ready to Use

Sinus Wash Kit (pre-filled with solution)

Read through entire section.

- 1. Wash your hands and remove cap and foil safety seal from the top of the pre-filled bottle.
- 2. Assemble white cap and tube and then place on pre-filled bottle and tighten securely.
- 3. 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.

- 4. 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.
- 5. 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.
- 6. 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.
- 7. Repeat the procedure on the left nostril with the remaining solution.
- 8. A small amount of solution will remain at the bottom of the bottle. Discard the remaining solution.
- 9. Thoroughly rinse the bottle after each use with water that has been either distilled, sterilized, filtered or previously boiled and leave the bottle open to air dry completely.
- 10. Bottle, tube and cap may be reused with included packets. See instructions that follow.

Isotonic Solution

Hypertonic Solution

1 Saline Packet per

8 fl oz. (240 mL)

2 Saline Packets per

8 fl oz. (240 mL)

Refill instructions for the Ready to Use

Sinus Wash Kit (with saline packets)

Read through entire section.

The Ready to Use Sinus Wash Kit can be used with the enclosed Saline packets to make either an Isotonic or Hypertonic solution. Check with the guide below or consult with your physician for best use.

An Isotonic solution creates a mild, less concentrated salt solution of 9 mg of Sodium Chloride per mL of water, which has a similar 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 creates a higher, more concentrated salt solution which is similar to the salt content of ocean water.

- 1. Wash your hands and make sure the bottle has been rinsed with water that has been either distilled, sterilized, filtered or previously boiled.
- 2. Pour the pre-mixed saline dry ingredients into the Squeeze Bottle. First-time users should start with 1 packet of the saline dry ingredients to make an isotonic solution. As you become more accustomed to the system, work up to using 2 full packets for a hypertonic solution. Additional packets may be purchased from your nearest pharmacy.
- 3. Fill the bottle to the 8 oz line with proper water*.
- 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. (continued on back) Hints for a more comfortable nasal wash:

- Begin using the Sinus Wash System slowly especially with children. 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 packet of dry ingredients per pot or 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 more 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.
- Some people experience irritation of the skin just inside 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



Product Information

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:59779-867

Packaging

l	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:59779-867-03	1 in 1 KIT	07/01/2014	

Quantity of Parts

Q au	quantity of 1 ares		
Part #	Package Quantity	Total Product Quantity	
Part 1	0 BOTTLE	3 g	
Part 2	1 PACKET	3000 mg	

Part 1 of 2

CVS

sodium bicarbonate, sodium chloride solution

Product Information

Item Code (Source)	NDC:59779-865
Route of Administration	NASAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
SODIUM BICARBONATE (UNII: 8 MDF5 V39 QO) (BICARBONATE ION - UNII: HN1ZRA3Q20)	SODIUM BICARBONATE	22.2 mg in .1 g	
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37)	SODIUM CHLORIDE	77.8 mg in .1 g	

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7)	

F	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 KIT		
1	NDC:59779-865- 00	240 g in 1 BOTTLE; 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		03/01/2016	

Part 2 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	1 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	

Marketing Information		
ation Number or Monograph Citation	Marketing Start Date	Marketing End Date
	07/01/2014	
	cation Number or Monograph Citation	cation Number or Monograph Citation Marketing Start Date

Labeler - CVS Pharmacy (062312574)

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