

LEADER SINUS WASH SALINE REFILL PACKETS- sodium bicarbonate, sodium chloride powder, for solution
Cardinal Health, 110 dba LEADER

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.

Leader 100ct Refills

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

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 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:

Children under 4 years:

See enclosed instruction sheet for complete directions

Use 1-2 packets per 8 fl
oz(240 mL)
up to every 2 hours as
needed
Consult a physician

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

Questions?

1-888-547-5492

Should I use an Isotonic or Hypertonic Solution?

Any Sinus Wash Device 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.

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

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.

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 pot or 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.

Sinus Wash Instructions

Read through entire instruction sheet before using for the first time.

DO NOT
USE WITH
UNFILTERED TAP
WATER.

See *Important Note
& Proper Water
Sources**



What is the Sinus Wash System?

The Sinus Wash System is an all natural and medically proven method for relieving allergies, nasal congestion, discomfort caused by dry air, sinus infections, rhinitis of pregnancy and soothes irritated nasal passages. It gently washes away mucus buildup from the nose and improves breathing.

Because it is gentle, the system can be used up to every 2 hours as needed. Some people use it as routinely as they brush their teeth while others use it only on days when they need it.

*Important Note & Proper Water Sources

Do not use with unfiltered tap water. Use either distilled, or sterile, or filtered (using a NSF/ANSI Std. 53 certified filter or a filter 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 Soft Tip Neti Pot:

Read through entire section before using for the first time.

Important: Before first use thoroughly rinse the pot with proper water.* Remove the soft comfort tip, clean with soap and water, rinse with proper water* and reinstall.

1. Wash hands.
2. Remove the cap from the Soft Tip Neti Pot.
3. Pour the pre-mixed saline dry ingredients into the Soft Tip Neti Pot. 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.
4. Fill the pot to the 8 oz. line with proper water.* This makes 1 cup (8 oz.) of solution.
5. Tighten the cap on the pot securely, place one finger over the spout and one over the hole on the cap and gently shake the pot until the dry ingredients have completely dissolved.
6. Proper head position allows solution to flow through the nose by gravity.
 - Lean over the sink with your head bent down so you are looking directly into the basin. Holding the pot in your right hand, gently insert the spout into your right nostril so that it forms a comfortable seal.
 - Rotate your head so that the right nostril is directly above the left. The forehead should remain higher than the chin. Raise the handle of the pot so that the solution enters the right nostril. In a few moments, the solution will begin to drain out the left nostril into the sink. Do not inhale or "snort" solution into the nose – breathe through your mouth.
7. Use approximately half the solution in the Soft Tip Neti Pot, exhale through both nostrils to clear them of excess mucus and solution. Gently blow your nose into a tissue.
8. Repeat the procedure on the left nostril using the remaining solution.
9. Thoroughly rinse the pot after each use with proper water* and leave the pot open to air dry completely. Remove the soft comfort tip, clean with soap and water, rinse with proper water,* allow to air dry completely and reinstall.



Instructions for Use of the Soft Tip Squeeze Bottle:

Read through entire section before using for the first time.

Important: Before first use thoroughly rinse the squeeze bottle and cap with proper water.* Remove the soft comfort tip, clean with soap and water, rinse with proper water* and reinstall.

1. Wash Hands.
2. Remove the cap from the squeeze bottle.
3. Pour the pre-mixed saline dry ingredients into the 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.
4. Fill the bottle with proper water* to the 8 oz. mark indicated on the bottle.
5. 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.
6. 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.
7. 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.
8. 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.
9. 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.
10. Repeat the procedure on the left nostril with the remaining solution.
11. A small amount of solution will remain in the bottom of the bottle. Discard the remaining solution.
12. Thoroughly rinse the bottle and cap after each use with proper water* and leave the bottle open to air dry completely. Remove the soft comfort tip, clean with soap and water, rinse with proper water,* allow to air dry completely and reinstall.



Inactive Ingredients

None



LEADER SINUS WASH SALINE REFILL PACKETS

sodium bicarbonate, sodium chloride powder, for solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0270
Route of Administration	NASAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM BICARBONATE (UNII: 8MDF5V39QO) (BICARBONATE ION - UNII:HN1Z RA3Q20)	SODIUM BICARBONATE	700 mg in 3 g
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37)	SODIUM CHLORIDE	2300 mg in 3 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0270-1	30 in 1 CARTON	04/01/2013	
1		3 g in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:70000-0270-2	100 in 1 CARTON	04/01/2013	
2		3 g 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		04/01/2013	

Labeler - Cardinal Health, 110 dba LEADER (063997360)

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