

**REXALL SINUS WASH SYSTEM SOFT TIP SQUEEZE BOTTLE- sodium bicarbonate, sodium chloride
Dolgencorp, LLC**

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.

Rexall Sinus Wash System/Kit- Soft Tip Squeeze bottle

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

-Nasal Stuffiness

-Runny nose

-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 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: 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 number and expiration date

Questions?

1-888-4-REXALL

Inactive Ingredients

None

Instructions for Use of the SinuCleanse Squeeze

Directions: Read through entire section before using for the first time.

1. Remove the cap from the SinuCleanse Squeeze bottle.
2. Pour the pre-mixed saline dry ingredients into the SinuCleanse 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.
3. Fill the bottle with a proper water source * leaving approximately 1/2 inch of air at the top of the bottle. This makes 1 cup (8 oz.) of solution.
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.
6. 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.

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 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.

9. Repeat the procedure on the left nostril with the remaining solution.

10. A small amount of solution will remain at the bottom of the bottle. Discard the remaining solution.

11. Thoroughly rinse the bottle after each use with water that has been distilled, sterilized, filtered or previously boiled and leave the bottle open to air dry completely. The SinuCleanse Squeeze Bottle is also top-rack dishwasher safe.

Hints for a more comfortable nasal wash

- Begin using the SinuCleanse System slowly. 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 1/2 of a packet of dry ingredients for the Neti Pot or 1 packet per Squeeze Bottle of the saline dry ingredients. Gradually work up to using the solution at full strength. Do not use less than 1/2 packet for the Neti Pot or 1 packet per Squeeze bottle.

-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 the use of the SinuCleanse System may need to be discontinued.

-Breathe continuously through the mouth when using the SinuCleanse 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.



REXALL SINUS WASH SYSTEM SOFT TIP SQUEEZE BOTTLE

sodium bicarbonate, sodium chloride kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55910-919
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55910-919-20	1 in 1 KIT	05/17/2021	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	20 PACKET	60000 mg

Part 1 of 1

REXALL SINUS WASH

sodium bicarbonate, sodium chloride powder, for solution

Product Information

Item Code (Source) NDC:55910-543

Route of Administration NASAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37)	SODIUM CHLORIDE	2300 mg in 3000 mg
SODIUM BICARBONATE (UNII: 8MDF5V39QO) (SODIUM CATION - UNII:LYR4M0NH37, BICARBONATE ION - UNII:HN1ZRA3Q20)	SODIUM BICARBONATE	700 mg in 3000 mg

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55910-543-20	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	

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unapproved drug other		05/17/2021	

Labeler - Dolgencorp, LLC (068331990)