PREMIXED SALINE PACKETS- sodium chloride, sodium bicarbonate granule, for solution

Shenzhen Kerui Int'l Trading Co., Ltd

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.

83879-001-01

Active ingredient

Sodium Chloride USP 2300mg Sodium Bicarbonate USP 700mg

Purpose

Nasal Wash

Uses

Relieve Nasal Passages From:

- ■Nasal symptoms from sinusitis, cold, flu ■Nasal allergies, dryness and Hay fever
- ■Sneezing, runny nose, nasal stuffiness
- ■IPost nasal drip and nasal congestion ■Removes nasal irritants (dust, pollen, animal dander, smoke etc)
- ■Promotes nasal and sinus drainage l
 ■Moisturizes dry nasal passages ■Helps reduce swelling of nasal membranes

Warnings

Do not use

- if saline packet is open, torn, or expired.
- with fully blocked nasal passages or during ear infection or blockage.
- unfiltered tap water, unless it has been previously boiled for at least five minutes and then cooled to lukewarm or body temperature, as boiling sterilizes the water. Other choice are distilled, micro-filtered (through 0.2 micron), reverse osmosis filtered, or commercially bottled water.

When using this product

Wash hands before using

Stop use and ask a doctor

if discomfort or unrelieved symptoms occur.

Keep out of reach of children.

Directions

Adults and children 4 years and	use 1-2 packets per 8 fl oz (240ml) up to every 2 hours as		
over:	needed		
Children under 4 years: Consult a physician			
Mixing one saline packet to 8 fl oz (240ml) of water creates an Isotonic saline solution			
(Hypertonic with 2 saline packets) that is PH balanced and preservative free.			
Isotonic solution	1 saline packet per 8 fl oz (240 ml)		
Hypertonic solution	2 saline packets per 8 fl oz (240 ml)		
An Isotopic solution has a gentle salt concentration of 9 mg of Sodium Chloride per ml of			

An Isotonic solution has a gentle salt concentration of 9 mg of Sodium Chloride per ml of water, similar to your body's salt level. It can be more comfortable for some initially than a stronger Hypertonic solution.

A Hypertonic solution has a higher salt concentration, akin to ocean water's salt content.

Other information

Store in a cool and dry place.

Inactive ingredients

None

Label



PREMIXED SALINE PACKETS

sodium chloride, sodium bicarbonate granule, for solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83879-001
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 3000 mg	
SODIUM CHLORIDE (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	2300 mg in 3000 mg	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
NDC:83879-001-	100 in 1 BOX	12/22/2023	
1	3000 mg in 1 BAG; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		12/22/2023	

Labeler - Shenzhen Kerui Int'l Trading Co., Ltd (699692787)

Establishment				
Name	Address	ID/FEI	Business Operations	
Shenzhen Kerui Int'l trading co., ltd.		699692787	label(83879-001), manufacture(83879-001)	

Revised: 12/2023 Shenzhen Kerui Int'l Trading Co., Ltd