

## **SIMPLY SALINE REFILL PACKETS- sinus wash powder, for solution GURUNANDA, 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.*

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### **Simply Saline Refill Packets**

#### **Active Ingredients**

Sodium Bicarbonate USP 515 mg

Sodium Chloride USP 1685 mg

#### **Purpose**

Nasal Wash

#### **Uses**

- Restores vital moisture to provide prompt relief for dry , crusted and inflamed nasal membranes due to chronic sinusitis, colds, low humidity, overuse of nasal decongestant drops and sprays, allergies, minor nose bleeds and other minor nasal irritations.
- Temporarily relieves nasal stuffiness.
- Reduces swelling of nasal passages; shrinks swollen membranes.
- Promotes nasal and/or sinus drainage; temporarily relieves sinus congestion and pressure.

#### **Warnings**

- **Do not exceed recommended dosage.**
- This product may cause temporary discomfort such as burning, stinging, sneezing or an increase in nasal discharge.
- The use of this container by more than one person may spread infection.

#### **Keep out of reach of children**

#### **Directions**

- Adults and children 4 years and over : Use 1-2 packets per 240 ml up to every 2 hours as needed
- Children under 4 years : Consult a physician

#### **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

## Inactive Ingredients

None

**Saline Solution**  
50 Saline Packets

ARM & HAMMER™ sinus wash products require you to mix 240 mL of purified water with one - 2.2 g Arm and Hammer™ premixed saline packet.

For best results please use as directed to ensure you get the best nasal rinsing experience and benefit. 1 packet per 240 mL of purified water.

**Simply Saline**  
50 Saline Refill Packets

Sinus washing may help symptoms of  
✓ Nasal Congestion  
✓ Dryness

Contents: 50 Saline Packets  
PACKET NET WT 0.08 oz (2.2 g) EACH

**Drug Facts**

**Active Ingredients** Purpose (in each packet)  
Sodium Bicarbonate USP 515 mg --- Nasal Wash  
Sodium Chloride USP 1685 mg ---- Nasal Wash

**Uses**

- Restores vital moisture to provide prompt relief for dry, crusty, and irritated nasal membranes due to chronic sinusitis, colds, low humidity, overuse of nasal decongestant drops and sprays, allergies, minor nose bleeds, and other minor nasal irritations.
- Temporarily relieves nasal stuffiness.
- Reduces swelling of nasal passages; shrinks swollen membranes.
- Promotes nasal and/or sinus drainage; temporarily relieves sinus congestion and pressure.

**Warnings**

- Do not exceed recommended dosage.
- This product may cause temporary discomfort such as burning, stinging, sneezing, or an increase in nasal discharge.
- The use of this container by more than one person may spread infection.

Keep out of reach of children

**Directions**

Adults and children 4 years and over: Use 1-2 packets per 8 oz (240 mL) up to every 2 hours as needed.

Children under 4 years: Consult a physician

**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

**Inactive ingredients**  
None

## SIMPLY SALINE REFILL PACKETS

sinus wash powder, for solution

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:70708-209 |
| <b>Route of Administration</b> | NASAL          |                           |               |

### Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength  | Strength           |
|---|--------------------|--------------------|
| <b>SODIUM BICARBONATE</b> (UNII: 8MDF5V39QO) (SODIUM CATION - UNII:LYR4M0NH37, BICARBONATE ION - UNII:HN1ZRA3Q20) | SODIUM BICARBONATE | 515 mg in 2200 mg  |
| <b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37)                                       | SODIUM CHLORIDE    | 1685 mg in 2200 mg |

### Inactive Ingredients

| Ingredient Name                 | Strength |
|---------------------------------|----------|
| <b>WATER</b> (UNII: 059QF0KO0R) |          |

### Product Characteristics

|                 |  |                     |  |
|-----------------|--|---------------------|--|
| <b>Color</b>    | white (WHITE CRYSTALLINE GRANULE POWDER) | <b>Score</b>        |  |
| <b>Shape</b>    |  | <b>Size</b>         |  |
| <b>Flavor</b>   |  | <b>Imprint Code</b> |  |
| <b>Contains</b> |  |                     |  |

### Packaging

| # | Item Code        | Package Description                                       | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:70708-209-02 | 50 in 1 BOX   | 10/01/2022           |                    |
| 1 |                  | 2200 mg in 1 POUCH; Type 1: Convenience Kit of Co-Package |                      |                    |

### Marketing Information

| Marketing Category       | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------------|--|----------------------|--------------------|
| unapproved drug<br>other |  | 10/01/2022           |                    |

**Labeler** - GURUNANDA, LLC (079671169)

**Registrant** - GURUNANDA, LLC (079671169)

Revised: 4/2023

GURUNANDA, LLC