NASALASALT ALL-NATURAL SEAWATER- sodium chloride spray Nasal and Sinus Health, Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

NASAL•ASALT™
ALL NATURAL SEAWATER SOLUTION
HYPERTONIC SALINE
MOISTURIZING
NASAL SPRAY

USES

Nas alAs alt[®] may be used 2-4 times per day to help provide fast temporary relief from swelling and congestion.

Use **Nas alAs alt**[®] as a prewash to help clear mucous buildup prior to using other nasal sprays.

DIRECTIONS

Tilt head forward, spray 2-3 times in each nostril directing spray upward and outward toward ear and away from center of nose. Blow nose. For best results, see package insert for the Vanderpool TechniqueTM for a more thorough nasal cleansing procedure or go to the NasalAsalt[®] web site for a video demonstration.

WARNINGS

Avoid spraying in eyes. Contents under pressure. Do not puncture or incinerate. Do not store at temperature above 120° F. Recommended storage at room temperature 59-86°F. Avoid direct exposure to sunlight.

Keep out of reach of children.

Do not use if tamper-evident seal is missing or torn on cap.

PRECAUTIONS

Do not use with children under 6 years of age except as directed by a physician. Use of this dispenser by more than one person may spread infection.

INGREDIENTS

Active Ingredient: Seawater 80%

Inactive Ingredient: Purified Water 20% Sterilized solution equivalent to 2.6% NaCl (sea salt)

Distributed by:

Nasal and Sinus Health, Inc., 16 Spring Hill Court, Bluffton, SC 29910. You may report serious side effects to this address.

PRINCIPAL DISPLAY PANEL - 100 mL Canister Carton

NASAL•ASALTTM

ALL NATURAL SEAWATER SOLUTION

HYPERTONIC SALINE MOISTURIZING NASAL SPRAY

Targets Nasal Dryness, Swelling and Congestion Caused by:

COLDS ALLERGIES

Additional Uses:
AS A NASAL CLEANSE AND
PREWASH SOLUTION

• To Help Clear Mucous Buildup Prior to Using Other Nasal Sprays

FOR COMFORT, HYGIENE AND NASAL & SINUS HEALTH

- To Soothe and Moisturize
- To Flush Out Allergens and Irritants

The Every Day Nasal Spray™

Preservative Free

3.38 FL OZ (100 mL)

Hypertonic Saline Nasal Spray

NASAL-ASALT" NASAL-ASALT"

ALL NATURAL SEAWATER SOLUTION

HYPERTONIC SALINE MOISTURIZING NASAL SPRAY

The Every Day Nasal Spray™

NasalAsalt® may be used daily for nasal dryness and discomfort due to:

- · Common cold & flu
- Allergies
- Nonallergic rhinitis
- · Environmental conditions
- Dry climate
- Aging
- Irritated nasal membranes

Recommended for:

- Routine nasal hygiene
- Maintenance of nasal and sinus health

NasalAsalt® is Safe, Natural and Convenient:

- Safe for daily use without risk of "nasal rebound congestion"
- No mixing and convenient to carry with you

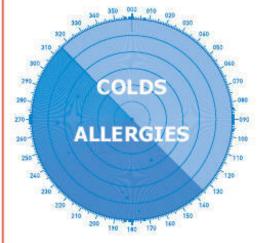
Money-Back Guarantee:

NasalAsalt® is backed by an unconditional, 60-day money-back guarantee. Simply return the unused contents in the original container with store receipt to Nasal and Sinus Health, Inc., P.O. Box 1850, Bluffton, SC 29910, within 60 days of

ALL NATURAL SEAWATER SOLUTION

HYPERTONIC SALINE MOISTURIZING NASAL SPRAY

Targets Nasal Dryness, Swelling and Congestion Caused by:



Additional Uses: AS A NASAL CLEANSE AND PREWASH SOLUTION

 To Help Clear Mucous Buildup Prior to Using Other Nasal Sprays

FOR COMFORT, HYGIENE AND NASAL & SINUS HEALTH

- To Soothe and Moisturize
 - To Flush Out Allergens and Irritants

The Every Day Nasal Spray™

purchase. Please allow up to 4 weeks to process the refund with our thanks for trying NasalAsalt®.

Preservative Free

3.38 FL OZ (100 mL)

www.NasalAsalt.com

Hypertonic Saline Nasal Spray

HYPERTONIC SALINE
MOISTURIZING
NASAL SPRAY

The Every Day Nasal Spray

ALL NATURAL SEAWATER SOLUTION

TASA-ARRA

NASAL-ASALT"

NASAL-ASALT™

ALL NATURAL SEAWATER
SOLUTION

HYPERTONIC SALINE MOISTURIZING NASAL SPRAY

The Event Day Nacel Cornell

USES

NasalAsalt® may be used 2-4 times per day to help provide fast temporary relief from swelling and congestion.

Use NasalAsalt® as a prewash to help clear mucous buildup prior to using other nasal sprays.

NasalAsalt®'s Advantages:

- Hypertonic to help reduce swelling naturally by osmosis
- Made from all natural seawater solution rich in mineral salts and trace elements for <u>soothing</u> and <u>effective</u> relief!
- Removable anatomically designed nozzle with one-way valve to help maintain sterility

The NasalAsalt® Result –
HELPS OPEN NASAL
PASSAGES AND
RELIEVE STUFFINESS
TO BREATHE EASIER!

NasalAsalt® is produced from prime tidewaters of the Atlantic Ocean off the coast of Brittany, France. Water quality at this location is monitored by French Water Authorities.



www.NasalAsalt.com

DIRECTIONS

Tilt head forward, spray 2-3 times in each nostril directing spray upward and outward toward ear and away from center of nose. Blow nose. For best results, see package insert for the Vanderpool Technique™ for a more thorough nasal cleansing procedure or go to the NasalAsalt® web site for a video demonstration.

WARNINGS

Avoid spraying in eyes. Contents under pressure. Do not puncture or incinerate. Do not store at temperature above 120° F. Recommended storage at room temperature 59-86°F. Avoid direct exposure to sunlight. Keep out of reach of children. Do not use if tamper-evident seal is missing or torn on cap.

PRECAUTIONS

Do not use with children under 6 years of age except as directed by a physician. Use of this dispenser by more than one person may spread infection.

INGREDIENTS

Active Ingredient: Seawater 80%
Inactive Ingredient: Purified Water 20%
Sterilized solution equivalent to 2.6% NaCl (sea salt)

Distributed by:

Nasal and Sinus Health, Inc., 16 Spring Hill Court, Bluffton, SC 29910. You may report serious side effects to this address. Made in Greece.

Hypertonic Saline Nasal Spray

NASALASALT ALL-NATURAL SEAWATER

sodium chloride spray

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52429-123
Route of Administration	NASAL		

Active Ingredient/Active Moiety

-						
Ing	re	die	nt	Na	m	e

Basis of Strength

Strength

Sodium Chloride (UNII: 451W47IQ8X) (Sodium Cation - UNII:LYR4M0NH37)

Sodium Chloride

 $2600\ mg$ in $100\ mL$

Inactive Ingredients

T		1:-		NT
ıng	re	are	nτ	Name

Strength

water (UNII: 059QF0KO0R)

Packaging

# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:52429-123-01	1 in 1 BOX		
1	100 mL in 1 CANISTER		

Marketing Information

0			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part349	11/0 1/20 11	

Labeler - Nasal and Sinus Health, Inc. (968415740)

Establishment

Name	Address	ID/FEI	Business Operations
Nasal and Sinus Health, Inc.		968415740	RELABEL

Establishment				
Name	Address	ID/FEI	Business Operations	
Gerolymatos International		423075886	MANUFACTURE	

Revised: 9/2011 Nasal and Sinus Health, Inc.