

**BREATHE THE SEA ALL-NATURAL SEAWATER- sodium chloride spray
Nasal and Sinus Health, Inc.**

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.

**Breathe the Sea™ All-Natural Seawater Solution
Hypertonic Nasal Spray**

USES

Helps dry congestion related to acute and chronic nasal stuffiness due to irritants, colds, occupational, environmental and home allergens. Provides comfort to congested nasal passages.

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 a more thorough cleansing procedure see the Vanderpool Technique™ and video demonstration at www.BreatheTheSea.com.

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. Avoid spraying in eyes.

CAUTION

Contents under pressure. Do not puncture or incinerate. Store at room temperature (59-86°F). Avoid direct exposure to sunlight.

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

KEEP OUT OF REACH OF CHILDREN

DISTRIBUTED BY

Nasal and Sinus Health, Inc.

16 Spring Hill Court

Bluffton, SC 29910

You may report any adverse effects to this address.

INGREDIENTS

Active Ingredient: Seawater 80%

Inactive Ingredient: Purified water 20% Sterilized solution is 2.6% NaCl (sea salt)

PRINCIPAL DISPLAY PANEL - 125 mL Canister Label

**ALL NATURAL SEAWATER
SOLUTION
HYPERTONIC NASAL SPRAY**

Breathe

the Sea[™]

The Every Day Nasal Spray[™]
Preservative Free

Use 2 – 4 times per day to:

- Help Dry Congestion
Due to Colds & Allergies
- Breathe Easier
- Soothe and Moisturize
- Flush out Allergens & Irritants
- Prewash Nasal Passages

4.22 fl. oz. (125 mL)

Tamper-Evident Seal
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**SAFE FOR DAILY USE
 ENVIRONMENTALLY FRIENDLY**

Breathe the Sea™ is made from prime seawater of the Atlantic Ocean off the coast of Brittany, France, rich in mineral salts and trace elements.

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 16 Spring Hill Court
 Bluffton, SC 29910
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Made in Greece

Breathe the Sea™ has a removable anatomically designed nozzle with a one-way valve to help maintain sterility.

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www.BreatheTheSea.com

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BREATHE THE SEA ALL-NATURAL SEAWATER

sodium chloride spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52429-124
Route of Administration	NASAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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Sodium Chloride (UNII: 451W47IQ8X) (Sodium Cation - UNII:LYR4M0NH37)	Sodium Chloride	2600 mg in 100 mL
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Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52429-124-01	125 mL in 1 CANISTER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		03/01/2012	

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: 2/2012

Nasal and Sinus Health, Inc.