

ENTSOL- sodium chloride spray
PharmaDerm, A division of Fougera Pharmaceuticals 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.

ENTSOL® SPRAY
Buffered Hypertonic Saline Nasal Spray

Recommended by leading ENTs, Allergists, and Pediatricians for fastacting, temporary relief...to enhance ciliary flow...as a pre-treatment for nasal steroid use. Reliable uniformity of dosage, buffered hypertonic saline nasal spray under pressure. Washes away allergens, dust, dirt and pollens.

Improves breathing. Clears congestion. Helps reduce nasal swelling. Helps relieve symptoms of sinusitis, allergies/ rhinitis, headaches, congestion, postnasal drip, and coughs due to postnasal drip. Effective treatment for preand post-surgical care. Pre-treatment for nasal steroid use.

Directions:

For best results, keep spray can in vertical position during use. Insert nozzle in one nostril. Lightly press down on applicator with finger to create spray.Repeat same procedure in other nostril. Spray 2 to 6 times daily or as instructed by a physician. Wipe nozzle clean after each use.

Ingredients:

Purified Water, Sodium Chloride, Sodium Phosphate - Dibasic, Potassium Phosphate - Monobasic.

Caution:

Contents under pressure. Do not dent or puncture can. Keep out of direct sunlight. Store and use at room temperature, between 15°- 30°C (59°-86°F). Please properly dispose of the container when the propellant is depleted. Note: It is not unusual that some liquid might remain in the container after all of the propellant is depleted. Use at room temperature only. Do not use if nose is completely blocked. Avoid oral consumption.

No CFCs - Environment Friendly

IL 133B R10/11

AN0795 0004

Active Ingredient:

Sodium chloride (3%)

Purpose:

Moisturizer

Uses:

- wash away allergens, dust, dirt & pollens
- increase ciliary flow
- improve breathing
- clear congestion
- help reduce nasal swelling

Warnings:

- Use at room temperature only
- Do not use if nose is completely blocked
- Avoid oral consumption

Directions:

- Important - Keep container in vertical position during use. Insert nozzle in one nostril.
- Lightly press down on applicator with finger.
- Repeat the same in other nostril.
- Spray 2 to 6 times daily or as instructed by a physician.
- Wipe nozzle clean after each use.

Other information:

- Contents under air pressure. Do not dent or puncture container.
- Keep container out of direct sunlight.
- Store at room temperature, 15° - 30°C (59° and 86°F).

Inactive Ingredients

Purified Water, Sodium Phosphate - Dibasic, Potassium Phosphate - Monobasic.

CARTON SEALED FOR YOUR PROTECTION.

Manufactured for

PharmaDerm®

A division of Fougera Pharmaceuticals Inc.

Melville, NY 11747 USA

www.pharmaderm.com

Manufactured by:

Laboratoires Chemineau

Vouvray, France

CE

0459

IC 142B R11/11

PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – CONTAINER

NDC 10337-311-10

**SAFE
PRESERVATIVE-FREE**
**ENTSOL[®]
SPRAY**

Buffered Hypertonic Saline Nasal Spray

**UNIQUE DELIVERY SYSTEM PROVIDES
MAXIMUM EFFECTIVENESS**

**APPLICATION: IMPORTANT - KEEP CONTAINER IN
VERTICAL POSITION DURING USE.**

1. Insert nozzle in one nostril.
2. Lightly press down on applicator with finger.
3. Repeat the same in other nostril.
4. Spray 2 to 6 times daily or as instructed by a physician.

Wipe nozzle clean after each use.

CAUTION: Use at room temperature only. Do not use if nose is completely blocked. Avoid oral consumption.

INGREDIENTS: Purified Water, Sodium Chloride, Sodium Phosphate - Dibasic, Potassium Phosphate - Monobasic.

Contents under air pressure. Do not dent or puncture container. Keep container out of direct sunlight. Store at room temperature, between 15°-30°C (59°-86°F).

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Melville, NY 11747 USA
www.pharmaderm.com

Manufactured by:
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Vouvray, France



PB083B R10/11
AB0360 0002



**ENVIRONMENT
FRIENDLY**

Contains No CFCs.
Meets Clean Air
Standards.



NDC 10337-311-10

**SAFE
PRESERVATIVE-FREE**
**ENTSOL[®]
SPRAY**

**Buffered Hypertonic
Saline Nasal Spray**

DRUG-FREE, NATURAL

**IMPORTANT PART OF A PROGRAM
TO BREATHE BETTER...FAST!**

- Wash away allergens, dust, dirt & pollens
- Increase ciliary flow
- Improve breathing
- Clear congestion
- Help reduce nasal swelling

 **PharmaDerm[®]**
100 mL Spray

**ENTSOL[®]
SININE**

PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – CARTON

NDC 10337-311-10

53a52x100

NDC 10337-311-10


SAFE PRESERVATIVE-FREE

ENTSOL[®] SPRAY

Buffered Hypertonic Saline Nasal Spray

DRUG-FREE, NATURAL

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UNIQUE DELIVERY SYSTEM PROVIDES MAXIMUM EFFECTIVENESS

ENTSOL[®]

Buffered Hypertonic Saline Nasal Spray



HELPS CLEAR STUFFINESS & PREVENT SINUS INFECTIONS

RECOMMENDED BY LEADING ENTs, ALLERGISTS AND PEDIATRICIANS FOR FAST-ACTING RELIEF...

- To enhance ciliary flow
- As pre-treatment for nasal steroid use

ENTSOL[®]

Buffered Hypertonic Saline Nasal Spray


DRUG-FREE, NATURAL

IMPORTANT PART OF A PROGRAM TO BREATHE BETTER...FAST!

- Wash away allergens, dust, dirt & pollens
- Increase ciliary flow
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ENVIRONMENT FRIENDLY


Contains No CFCs. Meets Clean Air Standards.

 PharmaDerm[®]

100 mL Spray

ENTSOL[®]

Buffered Hypertonic Saline Nasal Spray



HELPS CLEAR STUFFINESS & PREVENT SINUS INFECTIONS

HELPS RELIEVE SYMPTOMS:

- Sinusitis
- Allergies/Rhinitis
- Headaches
- Recurrent Sore Throats
- Congestion
- Post-Nasal Drip
- Coughs & Throat Irritations Due To Post-Nasal Drip
- Pre- and Post-Surgical Care
- Prior To Nasal Steroid Use


Reliable uniformity of dosage; pre-mixed, pre-measured.

ENTSOL[®] SPRAY

Buffered Hypertonic Saline Nasal Spray

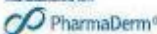
UNIQUE DELIVERY SYSTEM PROVIDES MAXIMUM EFFECTIVENESS

Drug Facts				
<table border="1"> <thead> <tr> <th>Active ingredient</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Sodium chloride (0.9%)</td> <td>Mucolytic</td> </tr> </tbody> </table>	Active ingredient	Purpose	Sodium chloride (0.9%)	Mucolytic
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Sodium chloride (0.9%)	Mucolytic			
Uses <ul style="list-style-type: none"> wash away allergens, dust, dirt & pollens increase ciliary flow improve breathing clear congestion help reduce nasal swelling 				
Warnings <ul style="list-style-type: none"> Use at room temperature only Do not use if nose is completely blocked Avoid oral consumption 				
Directions <ul style="list-style-type: none"> Important - Keep container in vertical position during use. Insert nozzle in one nostril. Lightly press down on applicator with finger. Repeat the same in other nostril. Spray 2 to 5 times daily or as instructed by a physician. Wipe nozzle clean after each use. 				
Other information <ul style="list-style-type: none"> Contents under air pressure. Do not dent or puncture container. Keep container out of direct sunlight. Store at room temperature, between 15°-30° C (59°-86° F) 				
Inactive ingredients purified water, sodium phosphate - dibasic, potassium phosphate - monobasic.				




See inside for further details.


CARTON SEALED FOR YOUR PROTECTION.

Manufactured for:  PharmaDerm[®]
A division of Roussel Pharmaceuticals Inc.
Menlo Park, NY 11747 USA
www.pharmaderm.com

Manufactured by: Laboratoires Chimieau Vouvray France

 CE

IC1429 R11/11 0450



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ENTSOL

sodium chloride spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10337-311
Route of Administration	NASAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:L YR4M0NH37)	SODIUM CHLORIDE	30 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	
POTASSIUM PHOSPHATE, MONOBASIC (UNII: 4J9FJ0HL51)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10337-311-10	1 in 1 CARTON		
1		100 mL in 1 BOTTLE, SPRAY		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		09/01/2000	

Labeler - PharmaDerm, A division of Fougera Pharmaceuticals Inc. (043838424)

Revised: 4/2012

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