

SALINE NASAL - sodium chloride spray

Promex, 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.

Drug Facts

Sodium Chloride 0.65%

Purpose

Moisturizer

Use

- For dry nasal membranes

Warnings

Do not use if seal is broken or missing.

Keep out of reach of children

The use of this dispenser by more than one person may spread infection.

Directions

- Squeeze twice in each nostril as needed
- Upright delivers a spray, horizontally a stream, upside down a drop

Inactive Ingredients

Boric acid, edetate disodium, polyhexamethylenebiguanide, purified water, sodium borate saline nasal spray

Drug Facts <table border="1"><thead><tr><th>Active ingredient</th><th>Purpose</th></tr></thead><tbody><tr><td>Sodium Chloride 0.65%.....</td><td>Moisturizer</td></tr></tbody></table> <p>Use • For dry nasal membranes</p> <p>Warnings Do not use if seal is broken or missing. Keep out of reach of children. The use of this dispenser by more than one person may spread infection.</p> <p>Directions • Squeeze twice in each nostril as needed • Upright delivers a spray, horizontally a stream, upside down a drop</p> <p>Inactive ingredients Boric acid, edetate disodium, polyhexamethylenebiguanide, purified water, sodium borate</p>	Active ingredient	Purpose	Sodium Chloride 0.65%.....	Moisturizer	 <p>Información del Medicamento</p> <table border="1"><thead><tr><th>Ingredientes activos</th><th>Propósito</th></tr></thead><tbody><tr><td>Cloruro de sodio 0,65%</td><td>Hidratante</td></tr></tbody></table> <p>Usos Para las membranas nasales secas</p> <p>Advertencias No utilice si el sello está roto o falta. Mantener fuera del alcance de los niños. El uso de este dispensador por más de una persona puede propagar la infección.</p> <p>Modo de empleo ■ Apriete dos veces en cada fosa nasal cuando sea necesario ■ Upright entrega un aerosol, un flujo horizontal, al revés una gota</p> <p>Ingredientes inactivos Acido bórico, edetato disódico, polihexametilenebiguanida, agua purificada, borato de sodio</p>	Ingredientes activos	Propósito	Cloruro de sodio 0,65%	Hidratante	<p>Made in Korea / Fabricado en Corea</p>  <p>1 84125 00184 2</p>
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Sodium Chloride 0.65%.....	Moisturizer									
Ingredientes activos	Propósito									
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Pro-Mex® 502 NE 190 St. Miami, FL 33179

NET / NETO 1.5 oz (44 mL)

Toll free / Gratis: 1 (855) 877-6639

LOT: EXP:

sodium chloride spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58988-0184
Route of Administration	NASAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:L4M0NH37)	SODIUM CHLORIDE	6.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
BORIC ACID (UNII: R57ZHV85D4)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
POLYAMINO PROPYL BIGUANIDE (UNII: 322U039GMF)	
WATER (UNII: 059QF0KO0R)	
SODIUM BORATE (UNII: 91MBZ8H3QO)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58988-0184-1	44 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		12/09/2013	

Labeler - Promex, LLC (789974388)

Revised: 12/2013

Promex, LLC