VORTEX MOISTURIZER NASAL- sodium chloride liquid Vortex Life Sciences, 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.

Vortex Moisturizer Nasal Spray

Drug Facts

Active Ingredients:

Sodium Chloride 0.65%

Purpose:

Moisturizer

Inactive Ingredient:

Purified mineral water

Uses

Temporary relief of dry irritated nasal passages Promotes healthy nasal passages Clears and invigorates breathing

Directions:

Sniff and inhale deeply while spraying into nostril.

12 years old- adult: 3 sprays in each nostril.

6 - 12 years old: 2 sprays in each nostril.

3 - 6 years old: 1 spray in each nostril.

Children under age 3: 1 spray. Consult a physician.

To use, remove cap, insert the nozzle into the nostril and depress the pump completely while sniffing deeply.

Day 1: every 3 hours, minimum 5 doses/day

Day 2: every 3 hours, minimum 5 doses/day

Day 3: 3 times a day.

Day 4: at bedtime.

Day 5: at bedtime.

Day 6 - 9: skip.

Day 10: Final dose at bedtime.

For moderate to severe symptoms every 3 hours (minimum 5 doses/24 hrs) until symptoms have significantly reduced. Then, resume at day 3 schedule.

WARNING:

Use only as directed.

If pregnant or breastfeeding,

consult with a physician before use.

Keep out of reach of children.

Stop use and consult with a physician

if you experience any discomfort while using this product.

In case of overdose, get medical help or contact a Poison Control Center at 1-800-222-2222 right away.

Other Information:

Store and use at room temperature Inspect bottle for integrity Do not use if safety seal is broken

Package Labeling:

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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.

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NDC#



MOISTURIZING NASAL SPRAY EXTRA STRENGTH

Breath Easy Feel Better

- Provides nonmedicated relief for dry and irritated nasal passages.
- Moisturizes and helps flush irritants from nasal passages.
- · All natural.
- · Drug free.
- · Preservative free.
- · Odor free.



Other Information:

Inspect bottle for integrity

Store and use at room temperature

Do not use if safety seal is broken

Lot:

Exp:



0.5 fl. oz. (15 mL) 120 measured sprays



FOR QUESTIONS OR COMMENTS:

1-800-XXX-XXX www.vortexcorpusa.com



VORTEX MOISTURIZER NASAL

sodium chloride liquid

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:82529-000 Route of Administration NASAL

Active Ingredient/Active Moiety

Ingredient Name

Basis of Strength

SODIUM CHLORIDE (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32ZN48698)

SODIUM CHLORIDE

6.5 mg in 1 mL

Inactive Ingredients						
Ingredient Name	Strength					
WATER (UNII: 059QF0KO0R)						

Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:82529-000- 01	1 in 1 BOX	03/01/2022			
1		15 mL in 1 BOTTLE; Type 0: Not a Combination Product				

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
unapproved drug other		03/01/2022			

Labeler - Vortex Life Sciences, Inc. (118489121)

Revised: 3/2022 Vortex Life Sciences, Inc.