VORTEX MOISTURIZER ORAL- phenol spray Vortex Life Sciences, 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.

Vortex Moisturizer Oral Spray

Drug Facts

Active Ingredients:

Phenol 0.7%

Purpose:

Anesthetic/Analgesic

Inactive Ingredient:

Purified mineral water

Uses

Relieves dry, sore and irritated throat

Directions:

12 years old - adult: 3 sprays.6 - 12 years old: 2 sprays.

3 - 6 years old: 1 spray.

Children under age 3: 1 spray. Consult a

physician.

To use, remove cap, depress the pump completely to spray directly into mouth

and throat.

Day 1: every 3 hours

Day 2: every 3 hours

Day 3: 3 times a day Day 4: at bedtime

Day 5: at bedtime

Day 6 - 9: skip

Day 10: at bedtime (final dose)

For moderate to severe symptoms every 3 hours (minimum 5 doses/24hrs) 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.

Sore Throat Warning

Severe or persistent sore throat or sore throat with high fever, headache, nausea and vomiting may be serious. Consult a doctor right away. Consult a doctor before giving to children under 3.

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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NDC#



MOISTURIZING ORAL SPRAY EXTRA STRENGTH

- Relief from mouth and throat dryness
- Relief from throat irritation and hoarseness
- · All natural
- · Drug free
- · Preservative free

0.5 fl. oz. (15 mL)

120 measured sprays

· Odor free



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FOR QUESTIONS OR COMMENTS:

1-800-880-1993 www.vortexcorpusa.com



Lot:

Exp:



Distributed By: Vortex Life Sciences Corp 11751 Monarch Street Garden Grove, CA 92841

VORTEX MOISTURIZER ORAL

phenol spray

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:82529-001

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength
I	PHENOL (UNII: 339NCG44TV) (PHENOL - UNII:339NCG44TV)	PHENOL	7 mg in 1 mL

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

ı	Packaging				
7	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
:	NDC:82529-001-	1 in 1 BOX	03/01/2022		
	L	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	
OTC monograph not final	part356	03/01/2022		
	part356	03/01/2022		

Labeler - Vortex Life Sciences, Inc. (118489121)

Revised: 3/2022 Vortex Life Sciences, Inc.