

SORE THROAT CHERRY- phenol spray
NuCare Pharmaceuticals, 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.

Drug Facts

Active ingredient

Phenol 1.4%

Purpose

Oral Anesthetic/Analgesic

Uses

temporarily relieves sore throat pain, sore mouth, pain associated with canker sores, minor mouth irritation

Warnings

Sore throat warning: Severe or persistent sore throat or sore throat that occurs with high fever, headache, nausea, and vomiting may be serious. Ask a doctor right away. Do not use more than 2 days or give to children under 3 years of age.

**When using this product,
do not use more than directed.**

Stop use and ask a doctor if

- swelling, rash or fever develops
- irritation, pain or redness persists or worsens
- sore mouth symptoms do not improve in 7 days
- difficulty in breathing occurs

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

- apply to affected area
- use every 2 hours
- allow to remain in place for at least 15 seconds, then spit out

age	dose
adults and children 12 years and over	for each application, spray 5 times
children 3 to 11 years	should be supervised in use of this product for each application, spray 3 times
children under 3 years	ask a doctor or dentist

Other information

- store at 20°-25°C (68°-77°F). Do not refrigerate.

Inactive ingredients

alcohol, FD&C red #40, glycerin, natural & artificial flavor, purified water, saccharin sodium

Questions or comments?

Call **1-877-753-3935 Monday-Friday 9AM-5PM EST**

Principal Display Panel

NuCare Pharmaceuticals, Inc.

NDC: 68071-1869-6

Sore Throat Spray

6oz Spray

Phenol 1.4%

See manufacturer's label for full list of ingredients.

Product #: R1647006

GTIN 00368071186963
Serial# 00000000002
Exp. Date 00-00
LOT#: 000000

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Rev 01/01/19
WARNING: KEEP OUT OF REACH OF CHILDREN
STORE AT CONTROLLED TEMPERATURE 68-77°F.

Distributed by: McKesson San Francisco, CA 94104
Packaged By: NuCare Pharmaceuticals, Inc. Orange, CA 92867

Use only as directed by your physician.

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SORE THROAT CHERRY

phenol spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68071-1869(NDC:49348-991)	
Route of Administration	ORAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
PHENOL (UNII: 339NCG44TV) (PHENOL - UNII:339NCG44TV)		PHENOL	1.4 g in 100 mL	
Inactive Ingredients				
Ingredient Name			Strength	
ALCOHOL (UNII: 3K9958V90M)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				
GLYCERIN (UNII: PDC6A3C0OX)				
WATER (UNII: 059QF0K00R)				
SACCHARIN SODIUM (UNII: SB8ZUX40TY)				
Product Characteristics				
Color		Score		
Shape		Size		
Flavor	CHERRY	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68071-1869-6	177 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/27/2017	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part356	09/30/2014		

Labeler - NuCare Pharmaceuticals, Inc. (010632300)

Establishment

Name	Address	ID/FEI	Business Operations
NuCare Pharmaceuticals, Inc.		010632300	relabel(68071-1869)