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 accompanied with high fever, headache, nausea, and vomiting may be serious. Consult doctor promptly. Do not use more than 2 days or administer to children under 3 years of age.

When using this product,

do not exceed recommended dose.

Stop use and ask a dentist or doctor if

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

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

• adults and children 6 years of age and older

- apply to affected area (one spray)
- allow to remain in place for at least 15 seconds, then spit out
- use every 2 hours as directed by a doctor or dentist
- children under 12 years of age should be supervised in the use of this product
- children under 6 years of age, consult a doctor or dentist

Other information

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

Inactive ingredients

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

Questions or comments?

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

Principal Display Panel



Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:68071-5112(NDC:49348-991) Route of Administration ORAL Active Ingredient/Active Moiety Ingredient Name Basis of Strength Strength

Inactive Ingredients		
Ingredient Name	Strength	
ALCOHOL (UNII: 3K9958V90M)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
GLYCERIN (UNII: PDC6A3C0OX)		
WATER (UNII: 059QF0KO0R)		
SACCHARIN SODIUM (UNII: SB8ZUX40TY)		

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:68071- 5112-6	177 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	11/18/2019	

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(68071-5112)	

Revised: 9/2022 NuCare Pharmaceuticals,Inc.