SORE THROAT RELIEF- phenol spray WinCo Foods, LLC

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 the 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 to report an adverse event call 800-824-1706 Monday-Friday 9am-4pm MST

Principal Display Panel

Compare to the active ingredient in Chloraseptic®

Instant Acting

Sore Throat Relief

Phenol/Oral Anesthetic

Alcohol 0.10%

Relieves Sore Throat Pain

Cherry Flavor

Artificially Flavored

FL OZ (mL)

*This product is not manufactured or distributed by Prestige Brands, Inc., distributor of Chloraseptic®.

TAMPER EVIDENT: DO NOT USE IF IMPRINTED WRAP AROUND THE CAP IS BROKEN OR TORN.

DISTRIBUTED BY:

WINCO FOODS LLC

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Package Label



SORE THROAT RELIEF phenol spray **Product Information** HUMAN OTC DRUG NDC:67091-267 **Product Type** Item Code (Source) **ORAL Route of Administration 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: 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		177 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	12/31/2014	12/31/2024		

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part356	12/31/2014	12/31/2024		

Labeler - WinCo Foods, LLC (056098817)

Revised: 10/2023 WinCo Foods, LLC