SORE THROAT CHERRY- phenol spray AAFES/Your Military Exchanges

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

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)
 - o 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

*Compare to the active ingredient in Chloraseptic®

Sore Throat Spray

Phenol 1.4%

Oral anesthetic/Analgesic

- Alcohol 0.10%
- Aspirin Free
- Sugar Free

Cherry Flavor

FL OZ (mL)

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

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL AROUND CAP IS BROKEN OR MISSING

Manufactured For

Your Military Exchanges

By: PL Developments

11865 S. Alameda St

Lynwood, CA 90262

Package Label



EXCHANGE SELECT Sore Throat Spray Cherry Flavor

SORE THROAT CHERRY

phenol spray

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55301-376
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: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

Product Characteristics			
Color	red	Score	

Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

ı	Packaging			
# Item Code		e Package Description	Marketing Start Date	Marketing End Date
	1 NDC:55301-376-06	177 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	12/31/2018	12/31/2024

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	12/31/2018	12/31/2024

Labeler - AAFES/Your Military Exchanges (001695568)

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