CHLORASEPTIC WARMING SORE THROAT- phenol spray Prestige Brands Holdings, 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.

Chloraseptic Warming Sore Throat Spray

Drug Facts

Active ingredient

Phenol 1.4%

Purpose

Oral pain reliever

Uses

for the temporary relief of occasional minor irritation, pain, sore mouth and sore throat.

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 give to children under 3 years of age unless directed by a doctor.

When using this product

do not exceed recommended dosage.

Stop use and ask a doctor or dentist 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.

If more than used for minor mouth or throat pain is accidentally swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

Adults and children 3 years of age and older:

- Apply to the affected area (one spray)
- Allow to remain in place for at least 15 seconds, then spit out
- Use every 2 hours or as directed by a doctor or dentist
 Children under 12 years of age should be supervised in the use of this product
 Children under 3 years of age: consult a doctor or dentist

Other information

- store at room temperature
- check expiration date before using
- contains FD&C yellow 5 (tartrazine) as a color additive

Inactive ingredients

caramel color, citric acid, FD&C yellow no. 5, FD&C yellow no.6, glycerin, flavors, purified water, saccharin sodium, sodium citrate, sucralose

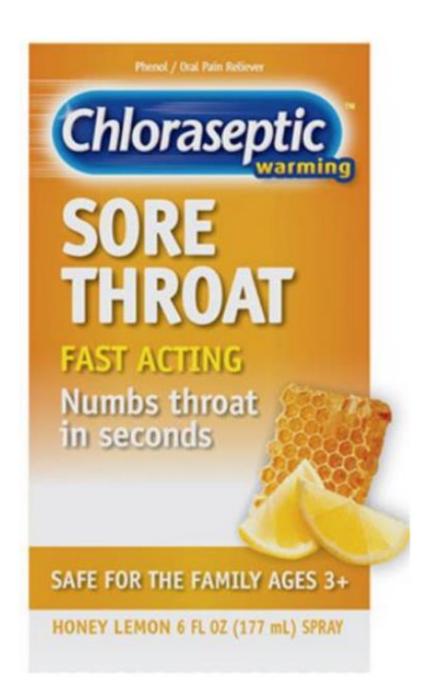
Questions?

1-800-552-7932

PRINCIPAL DISPLAY PANEL

Chloraseptic warming SORE THROAT

HONEY LEMON 6 FL OZ (177 mL) SPRAY



CHLORASEPTIC WARMING SORE THROAT

phenol spray

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:67172-212

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHENOI (INII: 330NCC44TV) (PHENOI LINII:330NCC44TV)	DHENOI	2.5 mg in 0.7 ml

Inactive Ingredients

Ingredient Name	Strength		
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)			
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)			
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)			
GLYCERIN (UNII: PDC6A3C0OX)			
WATER (UNII: 059QF0KO0R)			
SACCHARIN SODIUM (UNII: SB8ZUX40TY)			
SODIUM CITRATE (UNII: 1Q73Q2JULR)			
SUCRALOSE (UNII: 96K6UQ3ZD4)			

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		NDC:67172-212- 31	177 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2012	

Marketing Information				
Marketing Application Number or Monograph Category Citation		Marketing Start Date	Marketing End Date	
OTC monograph not final	part356	07/01/2012		

Labeler - Prestige Brands Holdings, Inc. (159655021)

Establishment					
Name	Address	ID/FEI	Business Operations		
Denison Pharmaceuticals, LLC		001207208	manufacture(67172-212)		

Revised: 4/2023 Prestige Brands Holdings, Inc.