

**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.*

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**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

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:67172-212
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>PHENOL</b> (UNII: 339NCG44TV) (PHENOL - UNII:339NCG44TV)	PHENOL	3.5 mg in 0.7 mL

### Inactive Ingredients

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

### Packaging

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

### Marketing Information

Marketing Category	Application Number or Monograph 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.