

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

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

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
PHENOL (UNII: 339NCG44TV) (PHENOL - UNII:339NCG44TV)	PHENOL	3.5 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)	

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 Drug	M022	07/01/2012	

Labeler - Prestige Brands Holdings, Inc. (159655021)

Establishment

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