

CHLORASEPTIC SORE THROAT CITRUS- phenol spray
CHLORASEPTIC SORE THROAT CHERRY- phenol spray
CHLORASEPTIC SORE THROAT MENTHOL- 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 Spray

Drug Facts

Active ingredient

Phenol 1.4%

Purpose

Oral Anesthetic/Analgesic

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 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 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 care professional before use.

Keep out of reach of children.

In case of overdose or accidental poisoning, get medical help or contact a Poison

Control Center 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.

Inactive ingredients

Citric acid, FD&C Red #40, FD&C Yellow #6, flavor, glycerin, purified water, sodium saccharin, sodium citrate

Questions?

1-800-552-7932 Chloraseptic.com

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- store at room temperature
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Inactive ingredients

FD&C red no. 40, flavors, glycerin, purified water, sodium chloride, sodium citrate, sodium saccharin, sucralose

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1-800-552-7932 Chloraseptic.com

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Other information

- store at room temperature
- check expiration date before using

Inactive ingredients

D&C green no. 5, D&C yellow no. 10, FD&C green no. 3, flavor, glycerin, purified water, sodium saccharin, sucralose

Questions?

1-800-552-7932 Chloraseptic.com

PRINCIPAL DISPLAY PANEL

Chloraseptic®
Phenol/Oral Anesthetic

CITRUS
6 FL OZ (177 mL)

**Sugar, Aspirin,
Gluten Free**

<p>Drug Facts</p> <table border="1" style="width: 100%; border-collapse: collapse;"><thead><tr><th style="text-align: left;">Active ingredient</th><th style="text-align: left;">Purpose</th></tr></thead><tbody><tr><td>Phenol 1.4%</td><td>Oral pain reliever</td></tr></tbody></table> <p>Uses for the temporary relief of occasional minor irritation, pain, sore mouth and sore throat.</p> <p>Warnings</p> <p>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.</p> <p>When using this product do not exceed recommended dosage.</p> <p>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</p> <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>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.</p> <p>Directions</p> <p>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</p> <p>Children under 12 years of age should be supervised in the use of this product.</p> <p>Children under 3 years of age: consult a doctor or dentist.</p> <p>Other information ■ store at room temperature ■ check expiration date before using</p> <p>Inactive ingredients citric acid, FD&C red no. 40, FD&C yellow no. 6, flavors, glycerin, purified water, sodium saccharin, sodium citrate</p> <p>Questions? 1-800-552-7932 Chloraseptic.com</p> <p style="text-align: center;">LIKE US ON </p>	Active ingredient	Purpose	Phenol 1.4%	Oral pain reliever	<p style="text-align: center;"><small>Tamper Evident: Do not use if original seal has been broken or missing.</small></p> <div style="text-align: center;"><p style="text-align: center;">0 78112 01255 0</p></div> <p style="text-align: center;"><small>(Use, by Medveten Products Inc., Torrington, NY 10591) A Private Consumer Healthcare company</small></p> <p style="text-align: center;"><small>©2012 Tropic Stress, a division of Medveten Products Inc. All rights reserved. CHUDMS001 Made in USA</small></p> <p style="text-align: center;"><small>For Lot and Expiration Date, see bottom of bottle.</small></p>	<div style="text-align: center;"><p style="text-align: center;">Phenol / Oral Pain Reliever</p><h1 style="text-align: center;">SORE THROAT</h1><ul style="list-style-type: none">■ FAST ACTING■ Numbs on Contact<div style="text-align: center;"><p style="text-align: center;">#1 DOCTOR RECOMMENDED</p></div><div style="text-align: center;"><p style="text-align: center;">CITRUS 6 FL OZ (177 mL)</p></div></div> <p style="writing-mode: vertical-rl; transform: rotate(180deg); font-size: small;">Some Clear Overlay, background elements only, no critical artwork</p>
Active ingredient	Purpose					
Phenol 1.4%	Oral pain reliever					

PRINCIPAL DISPLAY PANEL

Chloraseptic® Pheno/Oral Anesthetic

CHERRY Flavor

6 FL OZ (177 mL)



PRINCIPAL DISPLAY PANEL

Chloraseptic® Phenol/Oral Anesthetic

MENTHOL Flavor | 6 FL OZ (177 mL)



CHLORASEPTIC SORE THROAT CITRUS

phenol spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67172-112
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
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	

Product Characteristics

Color	orange	Score	
Shape		Size	
Flavor	CITRUS	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67172-112-31	177 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	09/01/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	09/01/2010	

CHLORASEPTIC SORE THROAT CHERRY

phenol spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67172-111
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
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color	red	Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67172-111-31	177 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	09/01/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	09/01/2010	

CHLORASEPTIC SORE THROAT MENTHOL

phenol spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67172-113
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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
D&C GREEN NO. 5 (UNII: 8J6RDU8L9X)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color	green	Score	
Shape		Size	
Flavor	MENTHOL	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67172-113-31	177 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	09/01/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	09/01/2010	

Labeler - Prestige Brands Holdings, Inc. (159655021)

Establishment

Name	Address	ID/FEI	Business Operations
Denison Pharmaceuticals, LLC		001207208	analysis(67172-112, 67172-111, 67172-113) , label(67172-112, 67172-111, 67172-113) , manufacture(67172-112, 67172-111, 67172-113) , pack(67172-112, 67172-111, 67172-113)

