

CHLORASEPTIC SORE THROAT (KIDS GRAPE) GRAPE- phenol spray
Denison Pharmaceuticals, LLC

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 Sore Throat Grape Spray

Drug Facts

Active ingredient

Phenol 0.5%

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

FD&C blue no. 1, FD&C red no.40, flavor, glycerin, purified water, sodium saccharin, sodium chloride

Questions?

1-800-552-7932 www.chloraseptic.com

PRINCIPAL DISPLAY PANEL

Kids Chloraseptic[®]

Phenol/Oral Anesthetic

SORE THROAT

Real Relief, Real Fast[®]

GRAPE | 6 fl oz (177 mL)

#1 Pharmacist Recommended

**NEW
Sprayer!
Same Formula**

ASPIRIN FREE • SUGAR FREE • GLUTEN FREE

Drug Facts	
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Phenol 0.5%	Oral anesthetic/Analgesthetic
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 7 days or administer to children under 3 years of age unless directed by 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 doctor before use.	
Keep out of reach of children. In case of overdose or accidental poisoning, 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.	
Inactive ingredients: FD&C blue no. 1, FD&C red no. 40, flavor, glycerin, purified water, sodium saccharin, sodium chloride	
Questions? 1-800-662-7832 chloraseptic.com	

Temporarily Glazed: Do not use if required alcohol based in formula or missing



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For Lot and Expiration Data, see bottom of bottle.

CH0402



CHLORASEPTIC SORE THROAT (KIDS GRAPE) GRAPE

phenol spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0295-9355
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
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	

Product Characteristics

Color	purple	Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0295-9355-23	177 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/07/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	03/07/2019	

Labeler - Denison Pharmaceuticals, LLC (001207208)

Establishment

Name	Address	ID/FEI	Business Operations
Denison Pharmaceuticals, Inc.		001207208	manufacture(0295-9355)

Revised: 3/2019

Denison Pharmaceuticals, LLC