SORE THROAT- phenol spray Raritan Pharmaceuticals 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.

DRx. Choice Sore Throat Spray Drug Facts

Active Ingredient(s)

Phenol 1.4%

Purpose

Oral pain reliever

Use(s)

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 that 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 6 years of age unless directed by doctor.

When using this product

do not exceed recommended dosage.

Stop use and ask a doctor 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

If more than used for minor mouth or throat pain is accidentally swallowed, get medical

help or contact a Poison Control Center right away. (1-800-222-1222).

Directions

- Adults and children 12 years of age and older:
 - Apply to the affected area (one spray). Allow to remain in place for at least 15 seconds, and then spit out.
- Use every 2 hours or as directed by a doctor or dentist.
- Children 6 years to under 12 years of age: should be supervised in the use of this product.
- Children under 6 years: Consult a doctor or dentist.

Other Information

- Store at room temperature
- Check expiration date before using.

Inactive Ingredients

FD&C Red No. 40, flavor, glycerin, purified water, sucralose

Questions or comments?

1-866-467-2748

Principal Display Panel

*Compare to the active ingredient in Chloraseptic®

NDC# 68163-703-06

SORE THROAT SPRAY

Phenol/Oral Pain Reliever

Fast Acting

Numbs on Contact

SUGAR-FREE

ASPIRIN-FREE

NATURAL CHERRY FLAVOR

6 FL OZ (177 mL)

Tamper-Evident: Do not use if imprinted shrink band is broken or missing.

Distributed by:

*This product is not manufactured or distributed by Prestige Brands Inc., owner of the registered trademark Chloraseptic®.





Drug Facts (continued)

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 right away at 1-800-222-1222.

Directions

Adults and children 12 years of age and older:
Apply to 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 a Children 6 years to under 12 years of age: Should be supervised in the use of this product. a Children under 6 years: Consult a doctor or dentist

Other information • Store at room temperature. • Check expiration date before using.

Inactive ingredients FD&C Red No. 40, flavor, glycerin, purified water, sucralose

Questions or comments? 1-866-467-2748

SORE THROAT

phenol spray

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:68163-703

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name

Basis of 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) SUCRALOSE (UNII: 96K6UQ3ZD4)

Product Characteristics

Color RED Score

Shape		Size	
Flavor	CHERRY (Natural Cherry)	Imprint Code	
Contains			

Packaging					
# Item Code	Package Description	Marketing Start Date	Marketing End Date		
1 NDC:68163-703-06	177 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	07/29/2020			

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part356	07/29/2020			

Labeler - Raritan Pharmaceuticals Inc (127602287)

Revised: 9/2023 Raritan Pharmaceuticals Inc