

NICE SORE THROAT SPEARMINT- phenol spray
Leosons Overseas Corp

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.

NICE Sore Throat Spearmint

Drug Facts

Active Ingredient & Purposes

Active Ingredients

Phenol 1.4%

Purposes

Oral Anesthetic/ Analgesic

Uses

For temporary relief of occasional minor irritation, pain, sore mouth, sore throat and pain associated with canker sores.

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 doctor.

When using this product

- do not use more than directed.

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
- difficulty in breathing occurs

If pregnant or breast feeding,

ask a health professional before use.

Keep this and all drugs out of reach of children.

In case of accidental overdose, seek professional assistance or contact a Poison Control Center right away.

Directions

- apply to the affected area
- 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

age

adults and children 12 years of age and older

dose

for each application, spray 5 times

children 3 to under 12 years
children under 3 years of age

should be supervised in use of this product
for each application, spray 3 times
consult a doctor or dentist

Other Information

- store at room temperature

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL IS TORN, BROKEN OR MISSING.

Inactive Ingredients

D&C green #5, D&C yellow #10, FD&C green #3, flavor, glycerin, propylene glycol, sodium saccharin, and water.

Questions?

1-855-452-9500 or email at info@leosonsintl.com

Distributed by:

LEOSONS
Albany, New York 12205
Made in USA

Principal Display Panel

SUGAR FREE • ALCOHOL FREE • ASPIRIN FREE

N'ICE®

P H E N O L / O R A L A N E S T H E T I C

Sore Throat Spray

Fast acting, long lasting relief of minor sore throat and mouth pain

SPEARMINT FLAVOR

6 FL OZ (177 mL)

Drug Facts (continued)

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NICE SORE THROAT SPEARMINT

phenol spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69626-0048
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 177 mL

Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GLYCERIN (UNII: PDC6A3C0OX)	
D&C GREEN NO. 5 (UNII: 8J6RDU8L9X)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	

Product Characteristics

Color	green	Score	
Shape		Size	
Flavor	SPEARMINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69626-0048-6	177 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/07/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	03/07/2014	

Labeler - Leosons Overseas Corp (148605470)