NICE SORE THROAT HONEY LEMON- 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.

N'ICE® Sore Throat Honey Lemon

Drug Facts

Active Ingredient & Purposes

Active Ingredients	Purposes
Phenol 1.4%	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 dose

adults and children 12 years of age and older children 3 to under 12 years children under 3 years of age

for each application, spray 5 times 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

caramel color, citric acid, FD&C yellow #6, flavor, glycerin, polysorbate 80, propylene glycol, sodium citrate, sodium saccharin, triacetin, 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®

PHENOL/ORALANESTHETIC

Sore Throat Spray

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

HONEY LEMON FLAVOR

6 FL OZ (177 mL)



NICE SORE THROAT HONEY LEMON

phenol spray

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:69626-0077

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHENOL (UNII: 339 NCG44TV) (PHENOL - UNII:339 NCG44TV)	PHENOL	1.4 g in 177 mL

Inactive Ingredients		
Ingredient Name	Strength	
GLYCERIN (UNII: PDC6A3C0OX)		
PROPYLENE GLYCOL (UNII: 6 DC9 Q16 7 V3)		
SACCHARIN SO DIUM (UNII: SB8 ZUX40 TY)		
WATER (UNII: 059QF0KO0R)		
SODIUM CITRATE (UNII: 1Q73Q2JULR)		
CITRIC ACID MONOHYDRATE (UNII: 2968 PHW8 QP)		
POLYSORBATE 80 (UNII: 6OZP39ZG8H)		
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)		
CARAMEL (UNII: T9D99G2B1R)		
TRIACETIN (UNII: XHX3C3X673)		

Product Characteristics			
Color	yellow	Score	
Shape		Size	
Flavor	HONEY (Honey Lemon)	Imprint Code	
Contains			

l	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:69626-0077-	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)

Revised: 12/2020 Leosons Overseas Corp