

NICE SORE THROAT CHERRY- 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 Cherry

Drug Facts

Active Ingredients & Purposes

| <i>Active Ingredients</i> | <i>Purposes</i> |
|----------------------------------|----------------------------|
| 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 | for each application, spray 5 times |
| children 2 to under 12 years | should be supervised in use of this product; |

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

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

citric acid, FD&C red #40, flavor, glycerin, propylene glycol, sodium citrate, sodium saccharin, and water.

Questions?

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

Distributed by:

LEOSONS

Albany, New York 12205

MADE IN THE USA

Principal Display Panel

- Sugar Free
- Alcohol Free
- Aspirin Free

N'ICE®

PHENOL/ ORAL ANESTHETIC

Sore Throat Spray

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

Cherry Flavor

6 FL OZ (177 mL)

SUGAR FREE • ALCOHOL FREE • ASPIRIN FREE

N'ICE®

PHENOL / ORAL ANESTHETIC

Sore Throat Spray

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

CHERRY FLAVOR **6 FL OZ (177 mL)**

Drug Facts (continued)

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 | for each application, spray 5 times |
| children 3 to under 12 years | should be supervised in use of this product for each application, spray 3 times |
| children under 3 years of age | consult a doctor or dentist |

Other information ■ store at room temperature

Inactive ingredients citric acid, FD&C red #40, flavor, glycerin, propylene glycol, sodium citrate, sodium saccharin, and water.

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MADE IN USA

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NICE SORE THROAT CHERRY

phenol spray

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:69626-0047 |
| 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 |
|--|----------|
| SACCHARIN SODIUM (UNII: SB8ZUX40TY) | |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| SODIUM CITRATE (UNII: 1Q73Q2JULR) | |
| WATER (UNII: 059QF0KO0R) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |

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:69626-0047-6 | 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)

