

**COOL RELIEF LEMON FROST ORAL ANESTHETIC- menthol lozenge**  
**Ricola USA 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.*

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**COOL RELIEF LEMON FROST ORAL ANESTHETIC**

**Drug Facts**

**Purpose**

Oral anesthetic

**Active Ingredient (in each drop)**

Menthol, 16.0 mg

**Uses**

temporarily relieves occasional minor irritation and pain associated with:

- sore mouth
- sore throat

**Warnings**

**Sore throat warnings:**

- if sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, swelling, nausea, or vomiting, consult a doctor promptly. These may be serious.

**Keep out of reach of children.**

**Directions**

- adults and children 6 years and older: dissolve 1 drop slowly in the mouth. Repeat every 2 hours as needed or as directed by a doctor
- children under 6 years: ask a doctor
- do not bite or chew

**Other Information**

protect from heat and moisture

**Inactive Ingredients**

citric acid, colors (carrot), extract of bee balm and the Ricola herb mixture (elder, horehound, hyssop, lemon balm, linden flowers, mallow, peppermint, sage, thyme, wild thyme), honey, lemon juice concentrate, starch syrup, sugar



COOL RELIEF LEMON FROST ORAL ANESTHETIC			
menthol lozenge			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63667-156
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)		MENTHOL	16.0 mg
Inactive Ingredients			
Ingredient Name			Strength
SUCROSE (UNII: C151H8M554)			
LEMON JUICE (UNII: AGN709ANTJ)			
HONEY (UNII: Y9H1V576FH)			
Product Characteristics			

<b>Color</b>	yellow	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	24mm
<b>Flavor</b>	LEMON	<b>Imprint Code</b>	R
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63667-156-19	19 in 1 PACKAGE; Type 0: Not a Combination Product	04/01/2019	
2	NDC:63667-156-24	24 in 1 PACKAGE; Type 0: Not a Combination Product	04/01/2019	
3	NDC:63667-156-45	45 in 1 PACKAGE; Type 0: Not a Combination Product	04/01/2019	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	04/01/2019	

**Labeler** - Ricola USA Inc. (177265261)

### Establishment

Name	Address	ID/FEI	Business Operations
Ricola Ag		485393768	manufacture(63667-156)

Revised: 4/2019

Ricola USA Inc.