

COOL RELIEF LEMON FROST ORAL ANESTHETIC- menthol lozenges

Ricola Ag

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.

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:54305-156
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)	
HONEY (UNII: Y9H1V576FH)	
LEMON JUICE (UNII: AGN709ANTJ)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54305-156-19	19 in 1 BAG; Type 0: Not a Combination Product	04/01/2019	
2	NDC:54305-156-45	45 in 1 BAG; Type 0: Not a Combination Product	04/01/2019	
3	NDC:54305-156-24	24 in 1 BAG; 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 Ag (480227248)

Establishment

Name	Address	ID/FEI	Business Operations
Ricola Ag		485393768	manufacture(54305-156)

Revised: 4/2019

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