

COOL RELIEF ORAL ANESTHETIC- menthol lozenge
Ricola Ag

COOL RELIEF ICY MENTHOL ORAL ANESTHETIC

Drug Facts

Purpose

Oral anesthetic

Active Ingredient (in each drop)

Menthol, 13.2 mg

Uses

temporarily relieves occasional minor irritation and pain associated with

- sore mouth
- sore throat

Warnings

Do not use

- in children under 5 years of age unless directed by a doctor

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

extract of lemon balm and the Ricola herb mixture (elder, horehound, hyssop, lemon balm, linden flowers, mallow, peppermint, sage, thyme, wild thyme), colors (carrot, spirulina), flavors (lemon-thyme, peppermint), starch syrup, sugar

Exp. Date/Batch:

Manufacturer:
Ricola Ltd.
4242 Laufen
Switzerland, www.ricola.com

For questions or comments, contact:
Ricola USA, Inc. (Distributor), 6 Campus Dr.,
2nd Floor South, Parsippany, NJ 07054

Product of Switzerland.




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9013222 US

From Switzerland



Ricola

COOL RELIEF
Icy Menthol
Sore Throat - Oral Anesthetic Drops



10 DROPS

Drug Facts	Drug Facts (continued)
<p>Active Ingredient (in each drop)</p> <p>Menthol 13.2 mg Oral anesthetic</p> <p>Uses temporarily relieves occasional minor irritation and pain associated with • sore mouth • sore throat</p> <p>Warnings Do not use</p> <ul style="list-style-type: none"> • in children under 5 years of age unless directed by a doctor. <p>Sore throat warnings:</p> <ul style="list-style-type: none"> • 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. <p>Keep out of reach of children.</p>	<p>Directions</p> <ul style="list-style-type: none"> • 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 <p>Other Information protect from heat and moisture</p> <p>Inactive Ingredients</p> <p>extract of lemon balm and the Ricola herb mixture (elder, horehound, hyssop, lemon balm, linden flowers, mallow, peppermint, sage, thyme, wild thyme), colors (carrot, spirulina), flavors (lemon-thyme, peppermint), starch syrup, sugar</p>

COOL RELIEF ORAL ANESTHETIC

menthol lozenge

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54305-513
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)		MENTHOL	13.2 mg	

Inactive Ingredients	
Ingredient Name	Strength
SUCROSE (UNII: C151H8M554)	

Product Characteristics			
Color	green	Score	no score
Shape	OVAL	Size	24mm
Flavor	MENTHOL (Icy Menthol)	Imprint Code	R
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54305-513-10	10 in 1 PACKAGE; Type 0: Not a Combination Product	02/01/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M022	02/01/2020	

Labeler - Ricola Ag (480227248)

Establishment			
Name	Address	ID/FEI	Business Operations
Ricola Ag		485393768	manufacture(54305-513)