

**COOL RELIEF ORAL ANESTHETIC- menthol lozenge**  
**Ricola USA Inc.**

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**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

					
<p>Exp. Date/Batch:</p>	<p>Manufacturer: Ricola Ltd. 4242 Laufen Switzerland, www.ricola.com</p> <p>For questions or comments, contact: Ricola USA, Inc. (Distributor), 6 Campus Dr., 2nd Floor South, Parsippany, NJ 07054</p> <p>Product of Switzerland.</p>	  <p style="text-align: right;">9013222 US</p>			
From Switzerland	<p><b>Ricola</b></p> <p><b>COOL RELIEF</b></p> <p>Icy Menthol Sore Throat • Oral Anesthetic Drops</p>	10 DROPS			
<p><b>Drug Facts</b></p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="width: 60%;">Active Ingredient (in each drop)</th> <th style="width: 40%;">Purpose</th> </tr> <tr> <td>Menthol 13.2 mg . . . . .</td> <td>Oral anesthetic</td> </tr> </table> <p><b>Uses</b> temporarily relieves occasional minor irritation and pain associated with • sore mouth • sore throat</p> <p><b>Warnings</b> Do not use</p> <ul style="list-style-type: none"> <li>• in children under 5 years of age unless directed by a doctor.</li> </ul> <p>Sore throat warnings:</p> <ul style="list-style-type: none"> <li>• 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.</li> </ul> <p>Keep out of reach of children.</p>	Active Ingredient (in each drop)	Purpose	Menthol 13.2 mg . . . . .	Oral anesthetic	<p><b>Drug Facts</b> (continued)</p> <p><b>Directions</b></p> <ul style="list-style-type: none"> <li>• 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</li> <li>• children under 6 years, ask a doctor</li> <li>• do not bite or chew</li> </ul> <p><b>Other Information</b> protect from heat and moisture</p> <p><b>Inactive Ingredients</b></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>
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## COOL RELIEF ORAL ANESTHETIC

menthol lozenge

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63667-513
<b>Route of Administration</b>	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:63667-513-10	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 USA Inc. (177265261)**Establishment**

Name	Address	ID/FEI	Business Operations
Ricola Ag		485393768	manufacture(63667-513)

Revised: 12/2024

Ricola USA Inc.