# RICOLA MAX THROAT CARE COOL PEPPERMINT- 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.

-----

#### RICOLA MAX THROAT CARE COOL PEPPERMINT

### **Drug Facts**

### **Purpose**

Cough suppressant, Oral anesthetic

# **Active Ingredient (in each drop)**

Menthol, 8.3 mg

#### Uses

temporarily relieves:

- cough due to a cold or inhaled irritants
- occasional minor irritation and pain due to sore throat or sore mouth

# **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.

# Ask doctor before use if you have

- persistent or chronic cough such as occurs with smoking, asthma, or emphysema
- cough accompanied by excessive phlegm (mucus)

# Stop use and ask a doctor if

- cough persists for more than 1 week, tends to recur, or is accompanied by fever, rash, or persistent headache. These could be signs of a serious condition.
- sore mouth does not improve in 7 days
- irritation, pain, or redness persists or worsens

# 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

Store in a dry place

### **Inactive Ingredients**

extract of peppermint and a Ricola herb mixture (elder, horehound, hyssop, lemon balm, linden flowers, mallow, peppermint, sage, thyme, wild thyme), glycerin, invert sugar (fructose/dextrose), natural flavor, starch syrup, sugar



# RICOLA MAX THROAT CARE COOL PEPPERMINT

menthol lozenge

### **Product Information**

**Product Type HUMAN OTC DRUG Item Code (Source)** NDC:63667-202

**Route of Administration** ORAL

# **Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength

**MENTHOL** (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) **MENTHOL** 8.3 mg

# **Inactive Ingredients**

Ingredient Name	Strenath

SUCROSE (UNII: C151H8M554)

**GLYCERIN** (UNII: PDC6A3C0OX)

### **Product Characteristics**

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

Contains

#### Packaging

# Item Code Package Description		Marketing Start Date	Marketing End Date
1 NDC:63667-202-	34 in 1 BAG; Type 0: Not a Combination Product	03/01/2022	2 3.00

# Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
OTC monograph final	part341	03/01/2022	

# Labeler - Ricola USA Inc. (177265261)

### Establishment

Establishinent			
Name	Address	ID/FEI	Business Operations
Ricola Ag		485393768	manufacture(63667-202)

Revised: 1/2023 Ricola USA Inc.