RICOLA MAX THROAT CARE HONEY LEMON- 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 HONEY LEMON

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.
- do not use in children under 6 years of age unless directed by a doctor.

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

citric acid, extract of a Ricola herb mixture (elder, horehound, hyssop, lemon balm, linden flowers, mallow, peppermint, sage, thyme, wild thyme), glycerin, honey, lemon juice concentrate, natural color (beta-carotene), natural flavors, starch syrup, sugar



menthol lozenge

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:63667-203

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	Strength

SUCROSE (UNII: C151H8M554)

GLYCERIN (UNII: PDC6A3C0OX)

Product Characteristics

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

Packaging

# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:63667-203-	34 in 1 BAG; Type 0: Not a Combination Product	03/01/2022	

Marketing Information

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

Labeler - Ricola USA Inc. (177265261)

Fstablishment

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Name	Address	ID/FEI	Business Operations
Ricola Ag		485393768	manufacture(63667-203)

Revised: 1/2023 Ricola USA Inc.