ORIGINAL HERB COUGH DROPS- 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.

ORIGINAL HERB COUGH DROPS

Drug Facts

Purpose

Cough supressant, Oral anesthetic

Active Ingredient (in each drop)

Menthol, 5.5 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 a 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 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. Do not bite or chew. Repeat every 2 hours as needed or as directed by a doctor
- children under 6 years: ask a doctor

Other Information

protect from heat and moisture

Inactive Ingredients

color (caramel), extract of a Ricola herb mixture (elder, horehound, hyssop, lemon balm, linden flowers, mallow, peppermint, sage, thyme, wild thyme), natural flavor, starch syrup, sugar

35.5mm



For questions or comments, contact Ricala USA, Inc. [Distributor), 6 Campus Dr., 2nd Hoor South, Parsing and Michael Poduct of Switzerland, Poduct of Switzerlan





Reclai

MADE WITH SWISS ALPINE HERBS

cough suppressant · oral anesthetic



9 DROPS

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ORIGINAL HERB COUGH DROPS

menthol lozenge

Product Type HUMAN OTC DRUG Item Code (Source) NDC:63667-933

Route of Administration ORAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) MENTHOL 5.5 mg

Inactive Ingredients		
	Ingredient Name	Strength

SUCROSE (UNII: C151H8M554)

Product Characteristics			
Color	red	Score	no score
Shape	RECTANGLE	Size	19mm
Flavor	MENTHOL (Herb)	Imprint Code	R
Contains			

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:63667-933- 09	9 in 1 PACKAGE; Type 0: Not a Combination Product	01/01/2022	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	01/01/2022	

Labeler - Ricola USA Inc. (177265261)

Establishment			
Name	Address	ID/FEI	Business Operations
Ricola Ag		480227248	manufacture(63667-933)

Revised: 1/2023 Ricola USA Inc.