NATURAL HONEY LEMON WITH ECHINACEA COUGH SUPPRESSANT THROAT 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.

NATURAL HONEY LEMON WITH ECHINACEA COUGH SUPPRESSANT THROAT DROPS

Drug Facts

Purpose

Cough suppressant, Oral anesthetic

Active Ingredient (in each drop)

Menthol, 3.5 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 doctor before use if you have

- persistent 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 2 drops (one at a time) slowly in the mouth. Repeat every 2 hours as needed or as directed by a doctor
- children under 6 years: ask a doctor

Other Information

Store in a dry place

Inactive Ingredients

ascorbic acid (vitamin C), citric acid, extracts of echinacea and a Ricola herb mixture (elder, horehound, hyssop, lemon balm, linden flowers, mallow, peppermint, sage, thyme, wild thyme), honey, lemon juice concentrate, natural flavors, starch syrup, sugar



NATURAL HONEY LEMON WITH ECHINACEA COUGH SUPPRESSANT THROAT DROPS

menthol lozenge

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:63667-960

Route of Administration ORAL

Active Ingredient/Active Moiety

l	Ingredient Name	Basis of Strength	Strength
ı	MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	3.5 mg

Inactive Ingredients			
Ingredient Name	Strength		
SUCROSE (UNII: C151H8M554)			
CORN SYRUP (UNII: 9G5L16BK6N)			
HONEY (UNII: Y9H1V576FH)			
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)			
ASCORBIC ACID (UNII: PQ6CK8PD0R)			
LEMON JUICE (UNII: AGN709ANTJ)			
ECHINACEA, UNSPECIFIED (UNII: 4N9P6CC1DX)			

Product Characteristics			
Color	yellow (HONEY YELLOW)	Score	no score
Shape	OVAL	Size	24mm
Flavor	LEMON (LEMON, HONEY, PEPPERMINT)	Imprint Code	R
Contains			

F	Packaging				
#	t Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:63667-960- 24	24 in 1 BAG; Type 0: Not a Combination Product	01/01/1942		
2	NDC:63667-960- 30	30 in 1 BAG; Type 0: Not a Combination Product	01/01/1942	01/01/2016	
3	NDC:63667-960- 45	45 in 1 BAG; Type 0: Not a Combination Product	01/01/1942		
4	NDC:63667-960- 19	19 in 1 BAG; Type 0: Not a Combination Product	01/01/2016		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	01/01/1942	

Labeler - Ricola USA Inc. (177265261)

Establishment			
Name	Address	ID/FEI	Business Operations
Ricola Ag		485393768	manufacture(63667-960)

Revised: 1/2023 Ricola USA Inc.