# SUGAR FREE LEMON MINT HERB 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.

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#### LEMON MINT HERB THROAT DROPS SUGAR FREE

## **Drug Facts**

#### **Purpose**

Oral anesthetic

## Active Ingredient (in each drop)

Menthol, 1.1 mg

#### Uses

temporarily relieves occasional minor irritation and pain associated with:

- sore mouth
- sore throat

## Warnings

#### Do not use

• in children under 6 years of age unless directed by a doctor.

#### Stop use and ask a doctor if

- sore throat is severe, persists for more than 2 days, or is accompanied by fever, headache, rash, nausea or vomiting.
- sore mouth symptoms do not improve in 7 days.

## Keep out of reach of children.

#### **Directions**

- adults and children 6 years and older: dissolve 3 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

- Phenylketonurics: contains phenylalanine 1 mg per drop
- excessive use may have a laxative effect
- store in a dry place
- product may be useful for diabetics on the advice of a doctor

Exchange information: 2 Drops = FREE Exchange

Dietary exchanges based on Exchange Lists for Diabetics

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## **Inactive Ingredients**

ascorbic acid (vitamin C), aspartame, citric acid, extracts of lemon balm and a Ricola herb mixture (elder, horehound, hyssop, lemon balm, linden flowers, mallow, peppermint, sage, thyme, wild thyme), isomalt, natural color (beta-carotene), natural flavors



SUGAR FREE LEMON MINT HERB THROAT DROPS				
menthol lozenge				
Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source) NDC:63667-956		67-956
Route of Administration	ORAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Str	ength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENT	HOL - UNII:L7T10EIP3A)	MENTHOL		1.1 mg

# **Inactive Ingredients**

Ingredient Name	Strength
Ingredient i une	Strength

ASPARTAME (UNII: Z0H242BBR1)

CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)

ISOMALT (UNII: S870P55O2W)

ASCORBIC ACID (UNII: PQ6CK8PD0R)

# **Product Characteristics**

Color	ye llo w	Score	no score
Shape	OVAL	Size	24mm
Flavor	LEMON (LEMON MINT)	Imprint Code	R

**Contains** 

Pa	ckaging			
#	Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date
1 N	NDC:63667-956-19	19 in 1 BAG; Type 0: Not a Combination Product	0 1/0 1/19 42	
2 N	NDC:63667-956-95	105 in 1 BAG; Type 0: Not a Combination Product	0 1/0 1/19 42	12/29/2017
3 N	NDC:63667-956-24	24 in 1 BAG; Type 0: Not a Combination Product	0 1/0 1/19 42	
4 N	NDC:63667-956-45	45 in 1 BAG; Type 0: Not a Combination Product	0 1/0 1/19 42	

# **Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	0 1/0 1/19 42	

# Labeler - Ricola USA Inc. (177265261)

# Establishment Name Address ID/FEI Business Operations Ricola Ag 480227248 manufacture(63667-956)

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