

## **NATURAL LEMON MINT HERB THROAT DROPS- menthol lozenge**

**Ricola Ag**

*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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## **NATURAL LEMON MINT HERB THROAT DROPS**

### **Drug Facts**

#### **Purpose**

Oral anesthetic

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

Menthol, 1.5 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 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

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



NATURAL LEMON MINT HERB THROAT DROPS

menthol lozenge

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54305-489
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)		MENTHOL	1.5 mg
Inactive Ingredients			
Ingredient Name			Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)			
SUCROSE (UNII: C151H8M554)			

## Product Characteristics

<b>Color</b>	yellow (GOLDEN YELLOW)	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	24mm
<b>Flavor</b>	LEMON (LEMON MINT)	<b>Imprint Code</b>	R
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54305-489-24	24 in 1 BAG; Type 0: Not a Combination Product	01/01/1942	
2	NDC:54305-489-30	30 in 1 BAG; Type 0: Not a Combination Product	01/01/1942	01/01/2016

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	01/01/1942	

**Labeler -** Ricola Ag (480227248)

## Establishment

Name	Address	ID/FEI	Business Operations
Ricola Ag		480227248	manufacture(54305-489)

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Ricola Ag