

## **THE ORIGINAL NATURAL HERB COUGH 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.*

-----

## **THE ORIGINAL NATURAL HERB COUGH DROPS COUGH SUPPRESSANT THROAT DROPS**

### **Drug Facts**

#### **Purpose**

Cough suppressant, Oral pain reliever

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

Menthol, 5.3 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 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

**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

<p><b>Drug Facts</b></p> <p><b>Active Ingredient (in each drop)</b> <b>Purposes</b>                  Menthol 5.3 mg.....Cough suppressant, Oral pain reliever</p> <p><b>Uses</b> temporarily relieves: •cough due to a cold or inhaled irritants                  •occasional minor irritation and pain due to sore throat or sore mouth</p> <p><b>Warnings</b>  <b>Sore throat warnings:</b> •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.  <b>Ask a doctor before use if you have</b> •persistent or chronic cough such as occurs with smoking, asthma, or emphysema                  •cough accompanied by excessive phlegm (mucus)  <b>Stop use and ask a doctor if</b> •cough persists for more than 1 week, tends to recur, or is accompanied by fever, rash, or persistent headache. ▶</p>		<p><b>Drug Facts (continued)</b></p> <p>These could be signs of a serious condition.                  •sore mouth does not improve in 7 days.                  •irritation, pain, or redness persists or worsens.  <b>Keep out of reach of children.</b></p> <p><b>Directions</b>                  •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.</p> <p><b>Inactive Ingredients:</b> 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.</p>	
 <p>0 36602 07992 2</p>		<p>Batch:</p> <p>Manufacturer: Ricola Ltd., 4242 Laufen, Switzerland Distributed by:                  Ricola USA Inc., 6 Campus Drive, 2nd Floor South, Parsippany, NJ 07054                  www.ricolausa.com, Product of Switzerland</p>	
<p><b>Effective Relief</b></p>  <p><b>From Switzerland</b></p>		<p><b>Ricola</b>®</p> <p>Natural Herb • Cough Suppressant • Throat Drops</p>  <p>10 Drops</p> <p>NDC 54305-923-10</p>	

**THE ORIGINAL NATURAL HERB COUGH DROPS**

menthol lozenge

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:54305-923
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	5.3 mg

**Inactive Ingredients**

Ingredient Name	Strength
SUCROSE (UNII: C151H8M554)	
CARAMEL (UNII: T9D99G2B1R)	

**Product Characteristics**

Color	brown (NUT BROWN)	Score	no score
Shape	RECTANGLE	Size	16mm
Flavor		Imprint Code	
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54305-923-10	10 in 1 PACKAGE; Type 0: Not a Combination Product	01/01/1942	

**Marketing Information**

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

**Labeler** - Ricola Ag (480227248)**Establishment**

Name	Address	ID/FEI	Business Operations
Ricola Ag		485393768	manufacture(54305-923)

Revised: 2/2020

Ricola Ag