

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

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Drug Facts (continued)

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Batch:

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

Effective Relief

From Switzerland

Ricola®

Natural Herb • Cough Suppressant • Throat Drops

NDC 54305-923-10

10 Drops

THE ORIGINAL NATURAL HERB COUGH DROPS

menthol lozenge

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:54305-923 |
| Route of Administration | 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) |