

**NATURAL HONEY HERB COUGH SUPPRESSANT 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.

NATURAL HONEY HERB COUGH SUPPRESSANT THROAT DROPS

Drug Facts

Purpose

Cough suppressant, Oral anesthetic

Active Ingredient (in each drop)

Menthol, 2.0 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 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

Store in a dry place

Inactive Ingredients

color (caramel), extract of Ricola's herb mixture (elder, horehound, hyssop, lemon balm, linden flowers, mallow, peppermint, sage, thyme, wild thyme), honey, natural flavors, starch syrup, sugar

FAIR TRADE HONEY

Ricola

MADE WITH SWISS ALPINE HERBS

COUGH SUPPRESSANT · ORAL ANESTHETIC

HONEY HERB®

great tasting soothing relief

24 WRAPPED DROPS

peppermint, sage, linden flower, lemon balm, hyssop, mallow, thyme

Since 1930 the Richterich family has made Ricola from naturally good Swiss Alpine herbs. Ricola is loved throughout the world for delicious taste and effective relief.

Grown on high Alpine slopes where the air is pure and the soil rich, Ricola herbs are cultivated by our farming partners.

Honey Herb

COUGH SUPPRESSANT · ORAL ANESTHETIC

Find out what the buzz is all about. Splendid subtle sweetness combines with our signature botanical blend to bring out the nurturing nature of real golden honey in these velvety herbal drops. A thrill for your throat and treat for your tastebuds, these delicious little drops deliver an uber smooth soothe whenever you need.

| Drug Facts | |
|--|---|
| Active Ingredient (in each drop) Menthol, 2.0 mg | Purposes Cough suppressant, Oral anesthetic |
| 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 a doctor before use if you have: • persistent or 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 3 drops (one at a time slowly) in the mouth. Do not bite or chew. • Repeat every 2 hours as needed or as directed by a doctor • children under 6 years: ask a doctor | |
| Other Information protect from heat and moisture | |
| Inactive Ingredients color (caramel), extract of a Ricola herb mixture (elder, horehound, hyssop, lemon balm, linden flowers, mallow, peppermint, sage, thyme, wild thyme), honey, natural flavors, starch syrup, sugar | |

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For questions or comments, contact:
Ricola USA, Inc. (Distributor), 6 Campus Dr.
2nd Floor South, Parsippany, NJ 07054

Manufacturer:
Ricola Ltd., 4242 Laufen, Switzerland
www.ricola.com Product of Switzerland

NATURAL HONEY HERB COUGH SUPPRESSANT THROAT DROPS

menthol lozenge

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:54305-108 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------------|-----------------|
| MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) | MENTHOL | 2.0 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|----------------------------|-----------------|
| SUCROSE (UNII: C151H8M554) | |
| CARAMEL (UNII: T9D99G2B1R) | |
| HONEY (UNII: Y9H1V576FH) | |

Product Characteristics

| | | | |
|-----------------|----------------------|---------------------|----------|
| Color | brown (golden brown) | Score | no score |
| Shape | OVAL | Size | 24mm |
| Flavor | HONEY | Imprint Code | R |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:54305-108-24 | 24 in 1 BAG; Type 0: Not a Combination Product | 01/01/1942 | |
| 2 | NDC:54305-108-30 | 30 in 1 BAG; Type 0: Not a Combination Product | 01/01/1942 | |
| 3 | NDC:54305-108-50 | 50 in 1 BAG; Type 0: Not a Combination Product | 01/01/2016 | |
| 4 | NDC:54305-108-45 | 45 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 Ag (480227248)**Establishment**

| Name | Address | ID/FEI | Business Operations |
|-------------|----------------|---------------|----------------------------|
| Ricola Ag | | 485393768 | manufacture(54305-108) |

