

**DUAL ACTION CHERRY COUGH SUPPRESSANT ORAL ANESTHETIC -
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.

DUAL ACTION CHERRY COUGH SUPPRESSANT ORAL ANESTHETIC

Drug Facts

Purpose

Cough suppressant, Oral anesthetic

Active Ingredient (in each drop)

Menthol, 8.3 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

Other Information

Store in a dry place

Inactive Ingredients

extract of a Ricola herb mixture (elder, horehound, hyssop, lemon balm, linden flowers, mallow, peppermint, sage, thyme, wild thyme), glycerin, malic acid, natural cherry concentrate, natural color, natural flavors, starch syrup, sugar

DUAL ACTION
Cough Suppressant • Oral Anesthetic Drops
Swiss Cherry
Soothes Cough
Relieves Sore Throat

Drug Facts

| Active Ingredient (in each drop) | Purpose(s) |
|----------------------------------|------------------------------------|
| Menthol, 8.5 mg..... | Cough suppressant, Oral anesthetic |

Uses temporarily relieve:
• cough due to a cold or viral 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, redness, 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. There could be signs of a serious condition. • sore throat 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

Other information protect from heat and moisture

Inactive ingredients extract of a Ricola herb mixture (elder, horehound, hyssop, lemon balm, linden flowers, mallow, peppermint, sage, thyme, wild thyme), glycerin, malic acid, natural cherry concentrate, natural color, natural flavors, starch syrup, sugar

9011772 US
Exp. Date: _____
Batch: _____

Ricola
DUAL ACTION
Cough Suppressant • Oral Anesthetic Drops

SOOTHES COUGH + **RELIEVES SORE THROAT**

Swiss Cherry
From Switzerland
19 DROPS

Ricola
Naturally Effective®

0 36602 30155 9

190 mm
7.5 mm
12.5 mm
155 mm
10 mm
5 mm
12.5 mm
46 mm
10 mm
130 mm
270 mm
10 mm
46 mm
15.5 mm
50 mm

DUAL ACTION CHERRY COUGH SUPPRESSANT ORAL ANESTHETIC
menthol lozenge

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:63667-224 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|-----------------|
| MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) | MENTHOL | 8.3 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|--------------------------------------|-----------------|
| SUCROSE (UNII: C151H8M554) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| MALIC ACID (UNII: 817L1N4CKP) | |

Product Characteristics

| | | | |
|-----------------|--------|---------------------|----------|
| Color | red | Score | no score |
| Shape | OVAL | Size | 24mm |
| Flavor | CHERRY | Imprint Code | R |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----------|------------------|---|-----------------------------|---------------------------|
| 1 | NDC:63667-224-19 | 19 in 1 BAG; Type 0: Not a Combination Product | 04/03/2011 | |
| 2 | NDC:63667-224-26 | 26 in 1 BAG; Type 0: Not a Combination Product | 04/03/2011 | |
| 3 | NDC:63667-224-75 | 175 in 1 BAG; Type 0: Not a Combination Product | 04/03/2011 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|---|-----------------------------|---------------------------|
| OTC monograph final | part341 | 04/03/2011 | |

Labeler - Ricola USA Inc. (177265261)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------|----------------|---------------|----------------------------|
| Ricola Ag | | 485393768 | manufacture(63667-224) |

