

SUGAR FREE LEMON MINT HERB THROAT DROPS- 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.

LEMON MINT HERB THROAT DROPS SUGAR FREE

Drug Facts

Purpose

Oral anesthetic

Active Ingredient (in each drop)

Menthol, 1.1 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 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

- Phenylketonurics: contains phenylalanine 1 mg per drop
- excessive use may have a laxative effect
- store in a dry place
- product may be useful for diabetics on the advice of a doctor

Exchange information: 2 Drops = FREE Exchange

7 Drops = 1 Fruit

Dietary exchanges based on Exchange Lists for Diabetics

© 2008 American Diabetes Association, American Dietetic Association

Inactive Ingredients

ascorbic acid (vitamin C), aspartame, citric acid, extracts of lemon balm and a Ricola herb mixture (elder, horehound, hyssop, lemon balm, linden flowers, mallow, peppermint, sage, thyme, wild thyme), isomalt, natural color (beta-carotene), natural flavors



SUGAR FREE LEMON MINT HERB THROAT DROPS

menthol lozenge

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:63667-956

| | |
|--------------------------------|------|
| Route of Administration | ORAL |
|--------------------------------|------|

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|----------|
| MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) | MENTHOL | 1.1 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| ASPARTAME (UNII: Z0H242BBR1) | |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) | |
| ISOMALT (UNII: S870P55O2W) | |
| ASCORBIC ACID (UNII: PQ6CK8PD0R) | |

Product Characteristics

| | | | |
|-----------------|--------------------|---------------------|----------|
| Color | yellow | Score | no score |
| Shape | OVAL | Size | 24mm |
| Flavor | LEMON (LEMON MINT) | Imprint Code | R |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:63667-956-19 | 19 in 1 BAG; Type 0: Not a Combination Product | 01/01/1942 | |
| 2 | NDC:63667-956-95 | 105 in 1 BAG; Type 0: Not a Combination Product | 01/01/1942 | |
| 3 | NDC:63667-956-90 | 210 in 1 BAG; Type 0: Not a Combination Product | 01/01/1942 | |
| 4 | NDC:63667-956-24 | 24 in 1 BAG; Type 0: Not a Combination Product | 01/01/1942 | |
| 5 | NDC:63667-956-45 | 45 in 1 BAG; 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 not final | part356 | 01/01/1942 | |

Labeler - Ricola USA Inc. (177265261)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------|---------|--------|---------------------|
| | | | |

Ricola Ag

480227248

manufacture(63667-956)

Revised: 1/2023

Ricola USA Inc.