ORIGINAL MENTHOL AND EUCALYPTUS SUGAR FREE- menthol lozenge Valda USA Labeler

ORIGINAL MENTHOL AND EUCALYPTUS SUGAR FREE

Drug Facts

Purpose

Cough suppressant, oral anesthetic

Active Ingredient (in each drop)

Menthol, 3.6 mg

Uses

Temporarily relieves:

- Minor sore throat
- Cough due to minor throat and bronchial irritation as may occur with a cold or inhaled irritants

Warnings

Sore throat warning: If sore throat is severe and persists for more than 2 days, is accompanied or followed by fever, headache, rash, swelling, nausea, or vomiting, consult a doctor promptly. These symptoms may be serious.

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 2 days
- Irritation, pain, or redness persists or worsens

Keep out of reach of children.

Directions

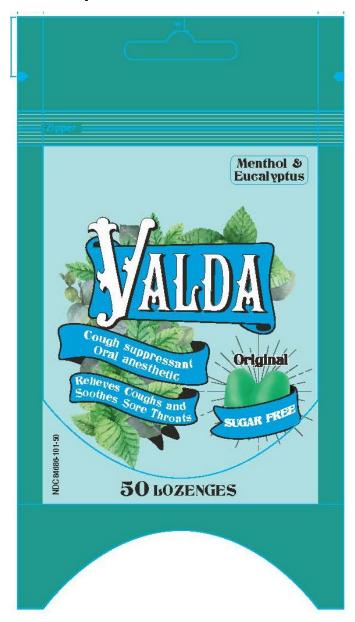
- Adults and children 5 years and over: Dissolve 2 drops (one at a time) slowly in mouth. Repeat every 2 hours as needed.
- Children under 5 years of age: Ask a doctor.

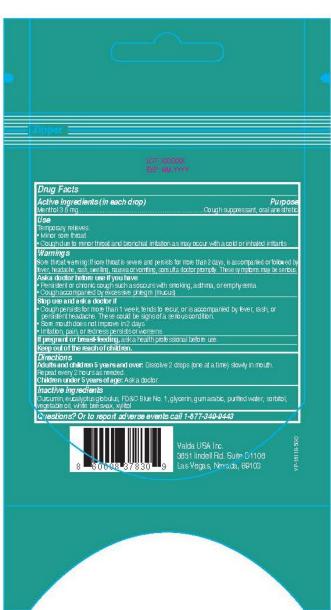
Inactive Ingredients

Curcumin, eucalyptus globulus, FD&C Blue No. 1, glycerin, gum arabic, purified water, sorbitol, vegetable oil, white beeswax, xylitol

Questions?

Or to report adverse events call 1-877-349-9443





ORIGINAL MENTHOL AND EUCALYPTUS SUGAR FREE

menthol lozenge

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:84686-101 Route of Administration ORAL

| Active Ingredient/Active Moiety | | | | |
|--|-------------------|----------|--|--|
| Ingredient Name | Basis of Strength | Strength | | |
| MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) | MENTHOL | 3.6 mg | | |

| Inactive Ingredients | | |
|--|----------|--|
| Ingredient Name | Strength | |
| CURCUMIN (UNII: IT942ZTH98) | | |
| EUCALYPTUS GLOBULUS WHOLE (UNII: SI1P2XF3M3) | | |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | | |
| GLYCERIN (UNII: PDC6A3C0OX) | | |
| ACACIA (UNII: 5C5403N260) | | |
| WATER (UNII: 059QF0KO0R) | | |
| SORBITOL (UNII: 506T60A25R) | | |
| CORN OIL (UNII: 8470G57WFM) | | |
| BEESWAX (UNII: 2ZA36H0S2V) | | |
| XYLITOL (UNII: VCQ006KQ1E) | | |
| | | |

| Product Characteristics | | | |
|-------------------------|--------------------------------|--------------|----------|
| Color | green (FD&C BLUE NO.1) | Score | no score |
| Shape | BULLET | Size | 13mm |
| Flavor | MENTHOL (MENTHOL & EUCALYPTUS) | Imprint Code | |
| Contains | | | |

| Packaging | | | | |
|-----------|----------------------|--|-------------------------|-----------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:84686-101- 50 | 50 in 1 PACKAGE; Type 0: Not a Combination Product | 12/02/2024 | |

| Marketing Information | | | |
|-----------------------|---|-------------------------|-----------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC Monograph Drug | M012 | 12/02/2024 | |
| | | | |

Labeler - Valda USA Labeler (119306540)

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------|---------|-----------|------------------------|
| Disch AG | | 480002609 | manufacture(84686-101) |

Revised: 12/2024 Valda USA Labeler